



(12) **United States Patent**
Hart et al.

(10) **Patent No.:** **US 9,421,034 B2**
(45) **Date of Patent:** **Aug. 23, 2016**

(54) **TROCAR SURGICAL SEAL**

(56) **References Cited**

(71) Applicant: **Applied Medical Resources Corporation**, Rancho Santa Margarita, CA (US)

U.S. PATENT DOCUMENTS

(72) Inventors: **Charles C. Hart**, Rancho Santa Margarita, CA (US); **John R. Brustad**, Rancho Santa Margarita, CA (US); **Jeremy J. Albrecht**, Rancho Santa Margarita, CA (US)

1,157,202 A	10/1915	Bates et al.
4,640,273 A	2/1987	Greene et al.
4,950,223 A	8/1990	Silvanov
4,984,564 A	1/1991	Yuen
5,144,942 A	9/1992	Decarie et al.
5,201,714 A	4/1993	Gentelia et al.
5,308,336 A	5/1994	Hart et al.
5,342,315 A	8/1994	Rowe et al.
5,342,385 A	8/1994	Norelli
5,360,417 A	11/1994	Gravener et al.

(Continued)

(73) Assignee: **Applied Medical Resources Corporation**, Rancho Santa Margarita, CA (US)

FOREIGN PATENT DOCUMENTS

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 163 days.

EP	1 698 291	9/2006
WO	WO01/26559	4/2001

(Continued)

(21) Appl. No.: **14/213,602**

OTHER PUBLICATIONS

(22) Filed: **Mar. 14, 2014**

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2014/028892, titled, Trocar Surgical Seal dated Sep. 24, 2015.

(Continued)

Prior Publication Data

US 2014/0276437 A1 Sep. 18, 2014

Related U.S. Application Data

(60) Provisional application No. 61/790,258, filed on Mar. 15, 2013.

Primary Examiner — Samuel Hanna

(74) *Attorney, Agent, or Firm* — Patrick Y. Ikehara

(51) **Int. Cl.**
A61B 17/34 (2006.01)
A61B 17/02 (2006.01)

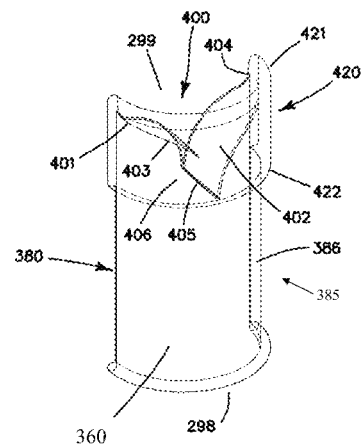
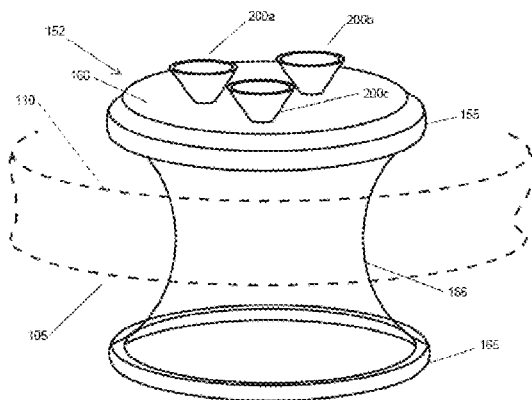
(57) **ABSTRACT**

(52) **U.S. Cl.**
CPC **A61B 17/3462** (2013.01); **A61B 17/0293** (2013.01); **A61B 17/3423** (2013.01)

A trocar surgical seal or surgical access device is provided. The trocar surgical seal comprises first and second supports coupled together by a film passageway. The trocar surgical seal provides an instrument seal for instruments inserted therethrough. The trocar surgical seal occupies minimal surgical space.

(58) **Field of Classification Search**
CPC A61B 17/0293; A61B 17/3423; A61B 17/3462; A61B 17/3431
See application file for complete search history.

14 Claims, 23 Drawing Sheets



(56)	References Cited		2004/0106942	A1	6/2004	Taylor et al.	
	U.S. PATENT DOCUMENTS		2004/0154624	A1	8/2004	Bonadio	
			2004/0167559	A1	8/2004	Taylor et al.	
			2004/0215063	A1	10/2004	Bonadio	
			2004/0254426	A1	12/2004	Wenchell	
			2004/0267096	A1*	12/2004	Caldwell	A61B 17/3423 600/213
5,366,478	A	11/1994	Brinkerhoff				
5,429,609	A	7/1995	Yoon				
5,441,486	A	8/1995	Yoon				
5,514,133	A	5/1996	Golub	2005/0148823	A1	7/2005	Vaugh
5,524,644	A	6/1996	Crook	2005/0155611	A1	7/2005	Vaugh
5,649,550	A	7/1997	Crook	2005/0192483	A1	9/2005	Bonadio et al.
5,752,938	A	5/1998	Flatland et al.	2005/0203346	A1	9/2005	Bonadio
5,782,817	A	7/1998	Franzel et al.	2005/0209510	A1	9/2005	Bonadio
5,788,676	A	8/1998	Yoon	2005/0209627	A1	9/2005	Kick et al.
5,810,721	A	9/1998	Mueller	2005/0261720	A1	11/2005	Caldwell
5,813,409	A	9/1998	Leahy	2005/0267419	A1*	12/2005	Smith
5,832,925	A	11/1998	Rothrum				A61B 17/3423 604/256
5,853,395	A	12/1998	Crook	2006/0142642	A1	6/2006	Lins
5,865,807	A	2/1999	Blake, III	2006/0161049	A1	7/2006	Beane
5,906,577	A	5/1999	Beane	2006/0161050	A1	7/2006	Butler
5,989,233	A	11/1999	Yoon	2006/0247498	A1	11/2006	Bonadio
5,993,485	A	11/1999	Beckers	2006/0247500	A1	11/2006	Voegel
6,007,544	A	12/1999	Kim	2007/0051375	A1	3/2007	Milliman
6,033,426	A	3/2000	Kaji	2007/0055107	A1	3/2007	Wenchell
6,033,428	A	3/2000	Sardella	2007/0088241	A1	4/2007	Brustad et al.
6,048,309	A	4/2000	Flom	2007/0093695	A1	4/2007	Bonadio
6,077,288	A	6/2000	Shimomura	2007/0203398	A1	8/2007	Bonadio
6,110,154	A	8/2000	Shimomura	2007/0239108	A1	10/2007	Albrecht et al.
6,142,935	A	11/2000	Flom	2007/0270752	A1	11/2007	Labombard
6,142,936	A	11/2000	Beane	2007/0299314	A1	12/2007	Bertolero
6,238,373	B1	5/2001	De la Torre et al.	2008/0011307	A1	1/2008	Beckman
6,254,533	B1	7/2001	Fadem	2008/0021362	A1	1/2008	Fihe
6,254,534	B1	7/2001	Butler	2008/0051733	A1	2/2008	Lynn
6,382,211	B1	5/2002	Crook	2008/0091080	A1	4/2008	Leahy
6,440,063	B1	8/2002	Beane	2008/0091143	A1	4/2008	Taylor et al.
6,450,983	B1	9/2002	Rambo	2008/0097162	A1	4/2008	Bonadio
6,485,467	B1	11/2002	Crook et al.	2008/0097163	A1	4/2008	Butler
6,582,364	B2	6/2003	Butler	2008/0146882	A1	6/2008	Cropper
6,589,167	B1	7/2003	Shimomura	2008/0146883	A1	6/2008	Kistler
6,613,952	B2	9/2003	Rambo	2008/0208222	A1	8/2008	Beckman
6,723,044	B2	4/2004	Pulford	2008/0249371	A1	10/2008	Beckman
6,814,078	B2	11/2004	Crook	2008/0249373	A1	10/2008	Wenchell
6,814,700	B1	11/2004	Mueller	2008/0300467	A1	12/2008	Schaefer
6,846,287	B2	1/2005	Bonadio	2009/0024097	A1	1/2009	Okoniewski
6,945,932	B1	9/2005	Caldwell	2009/0030375	A1	1/2009	Franer et al.
6,958,037	B2	10/2005	Ewers	2009/0036745	A1	2/2009	Bonadio
7,008,377	B2	3/2006	Beane	2009/0082631	A1	3/2009	Cronin
7,041,056	B2	5/2006	Deslauriers	2009/0082632	A1	3/2009	Voegel
7,081,089	B2	7/2006	Bonadio	2009/0118587	A1	5/2009	Voegel
7,153,261	B2	12/2006	Wenchell	2009/0149714	A1	6/2009	Bonadio
7,195,590	B2	3/2007	Butler	2009/0182282	A1	7/2009	Okihisa et al.
7,214,185	B1	5/2007	Rosney	2009/0187079	A1	7/2009	Albrecht et al.
7,294,103	B2	11/2007	Bertolero	2009/0227843	A1	9/2009	Smith
7,297,106	B2	11/2007	Yamada	2009/0281500	A1	11/2009	Acosta et al.
7,300,399	B2	11/2007	Bonadio	2009/0292176	A1	11/2009	Bonadio
7,390,317	B2	6/2008	Taylor et al.	2009/0306586	A1	12/2009	Ross et al.
7,393,322	B2	7/2008	Wenchell	2009/0326330	A1	12/2009	Bonadio
7,445,597	B2	11/2008	Butler	2009/0326332	A1	12/2009	Carter
7,473,221	B2	1/2009	Ewers et al.	2010/0030032	A1	2/2010	Voegel
7,481,765	B2	1/2009	Ewers et al.	2010/0063362	A1	3/2010	Bonadio
7,537,564	B2	5/2009	Bonadio	2010/0081880	A1	4/2010	Widenhouse
7,540,839	B2	6/2009	Butler	2010/0081881	A1	4/2010	Murray
7,559,893	B2	7/2009	Bonadio	2010/0081882	A1	4/2010	Hess
7,650,887	B2	1/2010	Nguyen et al.	2010/0081995	A1	4/2010	Widenhouse
7,678,046	B2	3/2010	White	2010/0094227	A1	4/2010	Albrecht et al.
7,686,823	B2	3/2010	Pingleton et al.	2010/0113882	A1	5/2010	Widenhouse
7,717,847	B2	5/2010	Smith	2010/0113883	A1	5/2010	Widenhouse
7,749,161	B2	7/2010	Beckman	2010/0145152	A1	6/2010	Smith
7,753,901	B2	7/2010	Piskun et al.	2010/0185057	A1	7/2010	Stearns
7,758,500	B2	7/2010	Boyd	2010/0204548	A1	8/2010	Bonadio
7,766,822	B2	8/2010	White	2010/0217087	A1	8/2010	Bonadio
7,766,824	B2	8/2010	Jensen	2010/0228090	A1	9/2010	Weisenburgh, II
7,819,800	B2	10/2010	Beckman	2010/0228091	A1	9/2010	Widenhouse
7,931,623	B2	4/2011	Wing et al.	2010/0228092	A1	9/2010	Ortiz
7,998,068	B2	8/2011	Bonadio et al.	2010/0228094	A1	9/2010	Ortiz
2001/0037053	A1	11/2001	Bonadio	2010/0240960	A1	9/2010	Richard
2002/0002324	A1	1/2002	McManus	2010/0249516	A1	9/2010	Shelton, IV
2003/0187376	A1	10/2003	Rambo	2010/0249520	A1	9/2010	Shelton, IV
2003/0192553	A1	10/2003	Rambo	2010/0249521	A1	9/2010	Shelton, IV
2004/0092796	A1	5/2004	Butler	2010/0249525	A1	9/2010	Shelton, IV

(56)

References Cited

U.S. PATENT DOCUMENTS

2010/0249526	A1	9/2010	Shelton, IV
2010/0249694	A1	9/2010	Choi
2010/0261970	A1	10/2010	Shelton, IV
2010/0261972	A1 *	10/2010	Widenhouse A61B 17/3462 600/206
2010/0261974	A1	10/2010	Shelton, IV
2010/0261975	A1	10/2010	Huey
2010/0262080	A1	10/2010	Shelton, IV
2010/0268035	A1	10/2010	Oberländer
2010/0274093	A1	10/2010	Shelton, IV
2010/0280326	A1	11/2010	Hess
2010/0280327	A1	11/2010	Nobis
2010/0280368	A1	11/2010	Can et al.
2010/0280437	A1	11/2010	Murr
2011/0066001	A1	3/2011	Shelton et al.
2011/0172495	A1	7/2011	Armstrong
2011/0251465	A1	10/2011	Kleyman
2012/0095297	A1	4/2012	Dang et al.
2012/0130184	A1	5/2012	Richard
2012/0157781	A1	6/2012	Kleyman
2012/0157782	A1	6/2012	Alfieri
2012/0157783	A1	6/2012	Okoniewski

2012/0157786	A1	6/2012	Pribanic
2012/0245430	A1	9/2012	Kleyman et al.
2012/0253134	A1	10/2012	Smith
2012/0253136	A1	10/2012	Rodrigues
2012/0283519	A1	11/2012	Nguyen et al.
2013/0018230	A1	1/2013	Su et al.

FOREIGN PATENT DOCUMENTS

WO	WO 03/034908	5/2003
WO	WO 03/103548	12/2003
WO	WO 2004/030547	4/2004
WO	WO 2006/082572	8/2006
WO	WO2010/045253	4/2010
WO	WO2010082722	7/2010
WO	WO2010104259	9/2010
WO	WO2012/044959	4/2012

OTHER PUBLICATIONS

European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2014/028892, mailed Jun. 24, 2014, entitled "Trocar Surgical Seal".

* cited by examiner

FIG. 1

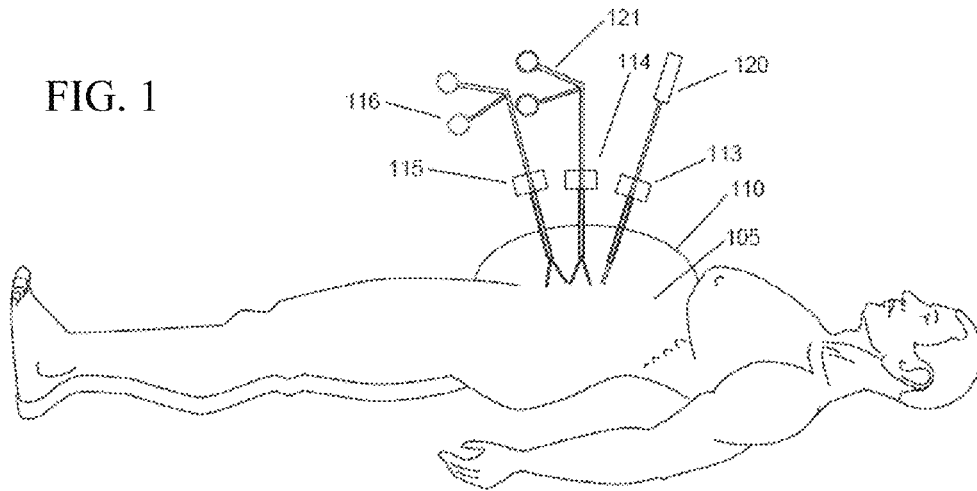


FIG. 2

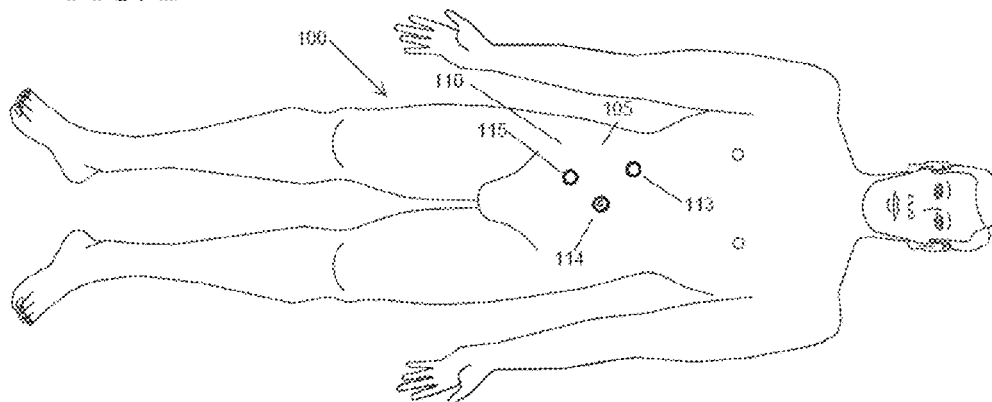


FIG. 3

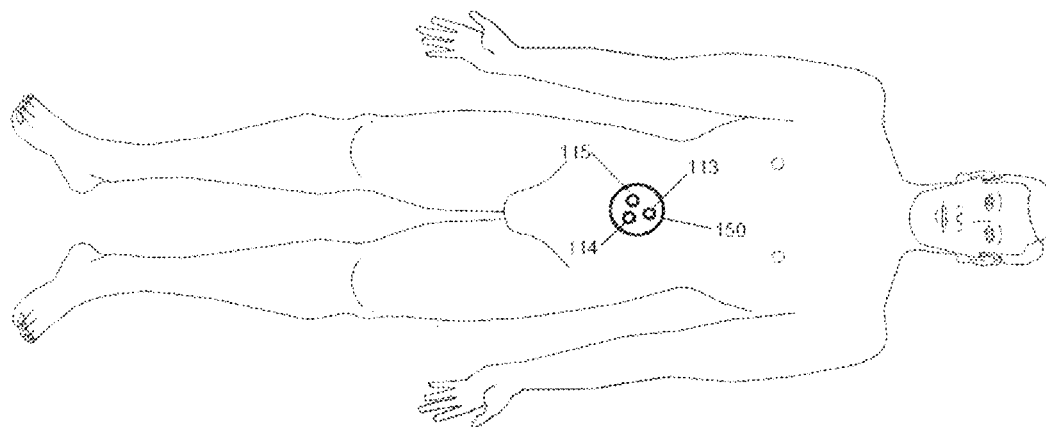
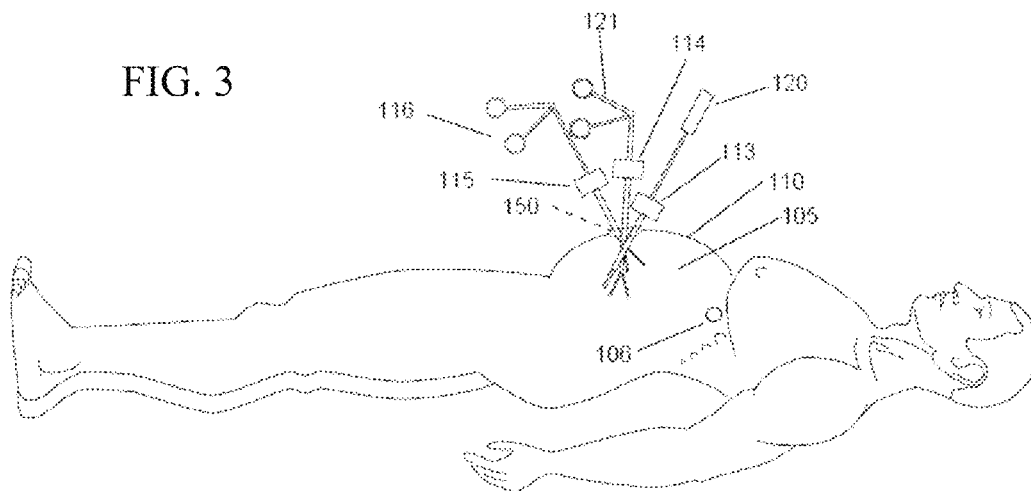


FIG. 4

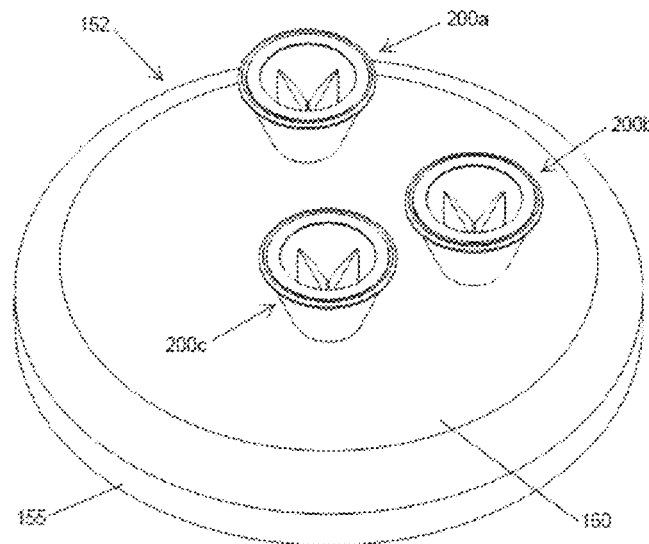


FIG. 5

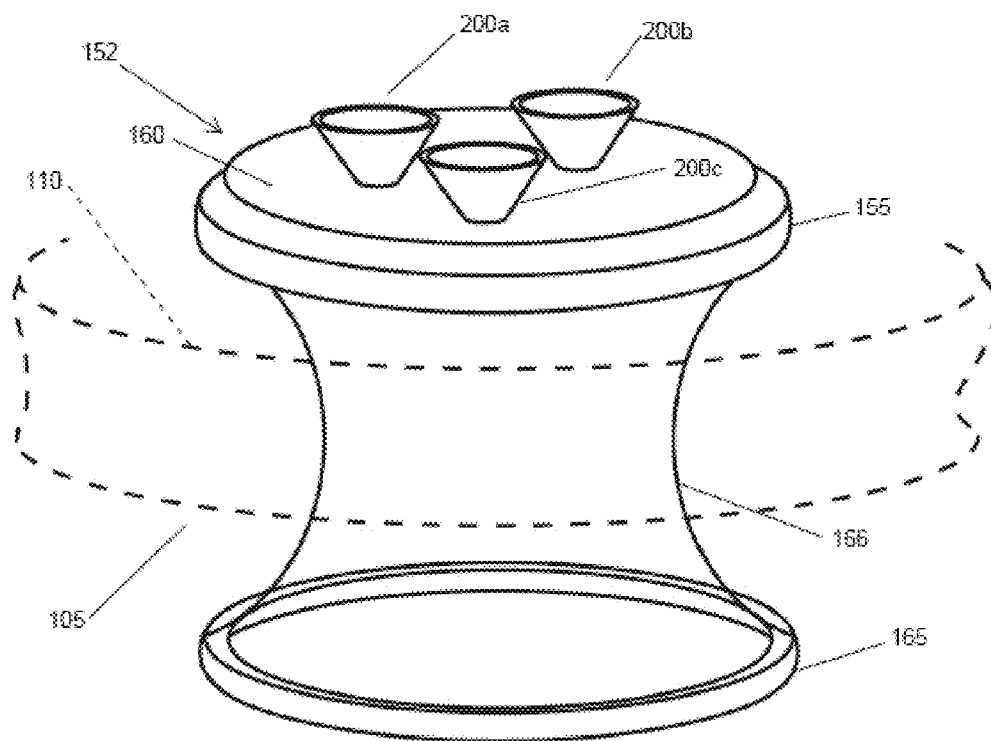


FIG. 6

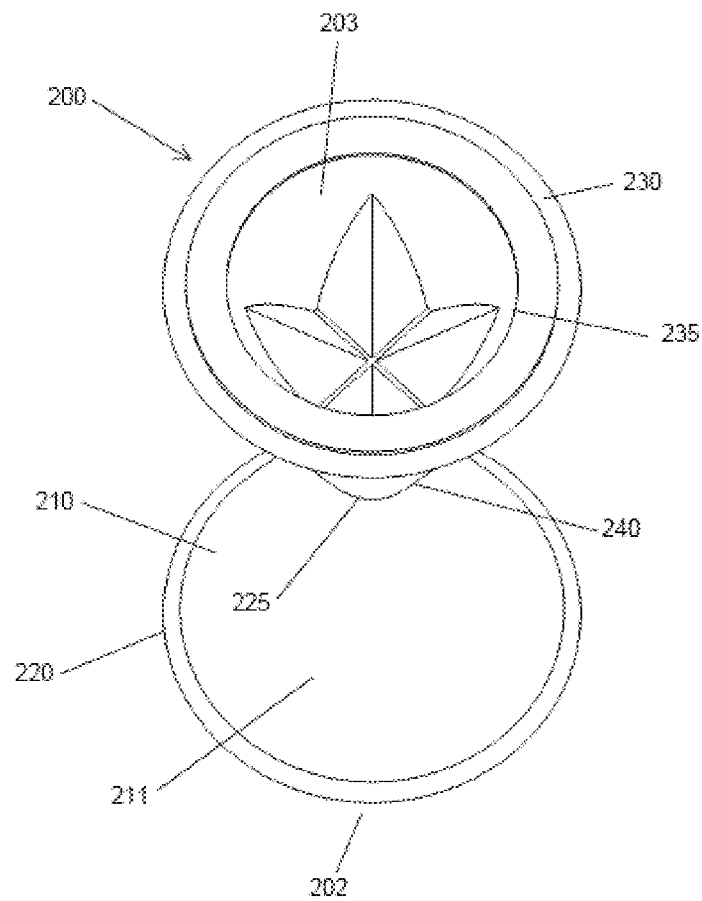


FIG. 7

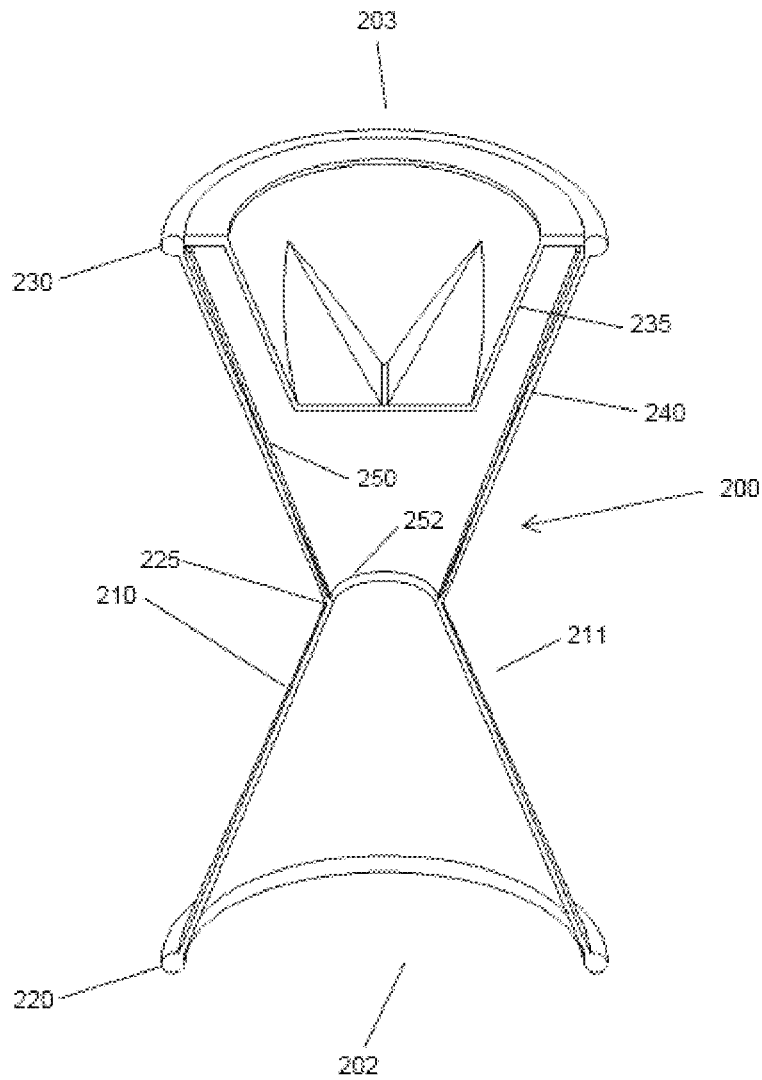


FIG. 8

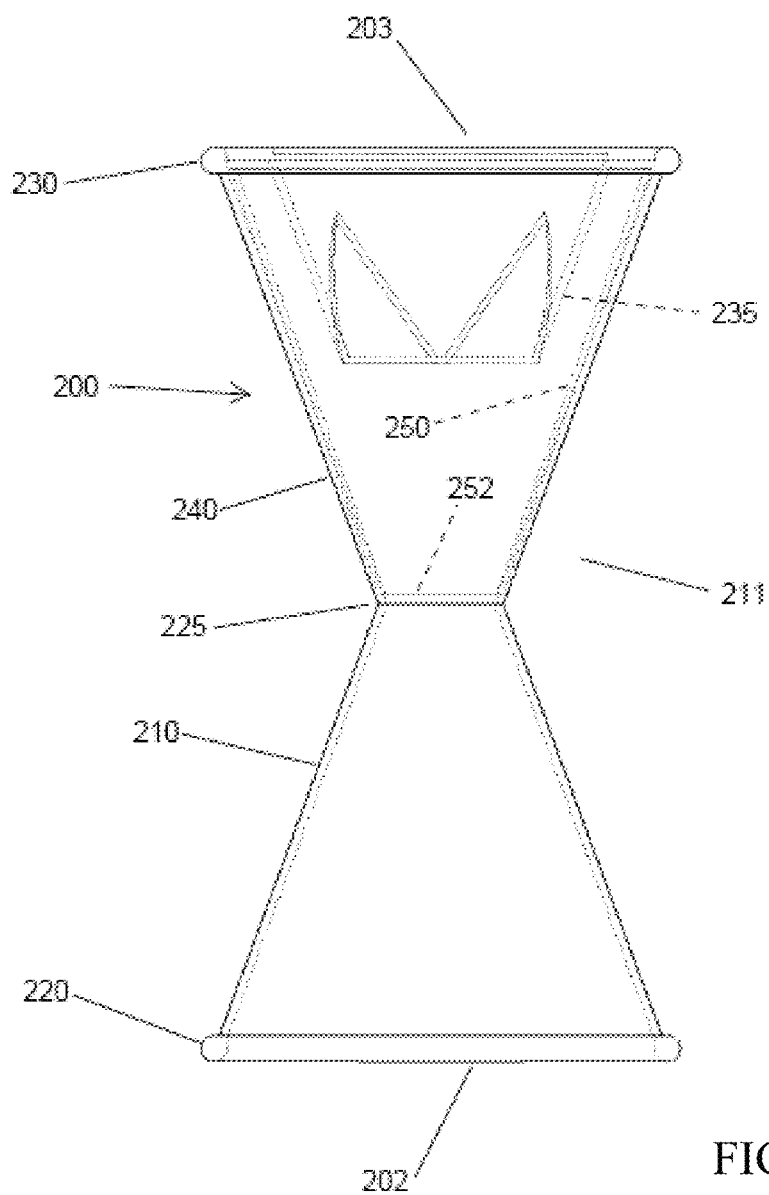


FIG. 9

FIG. 10

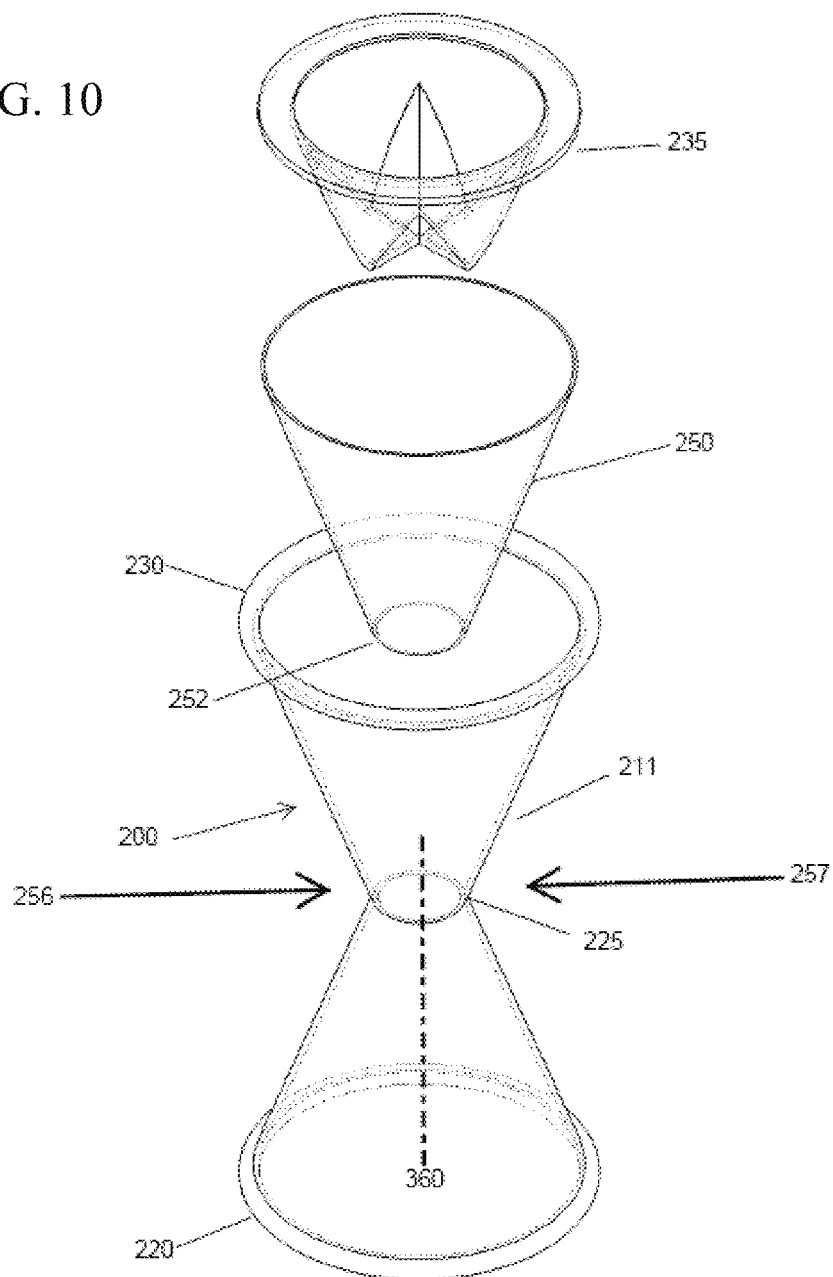


FIG. 11

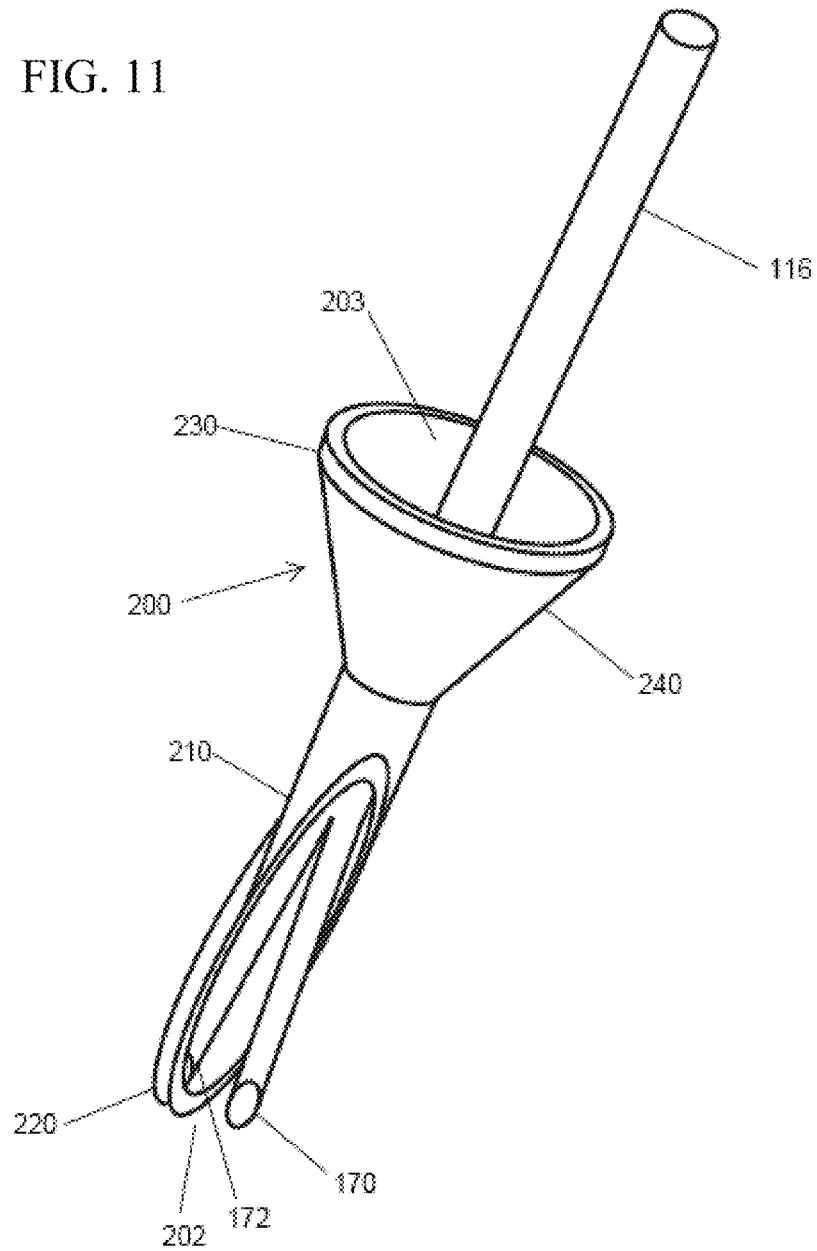


FIG. 12

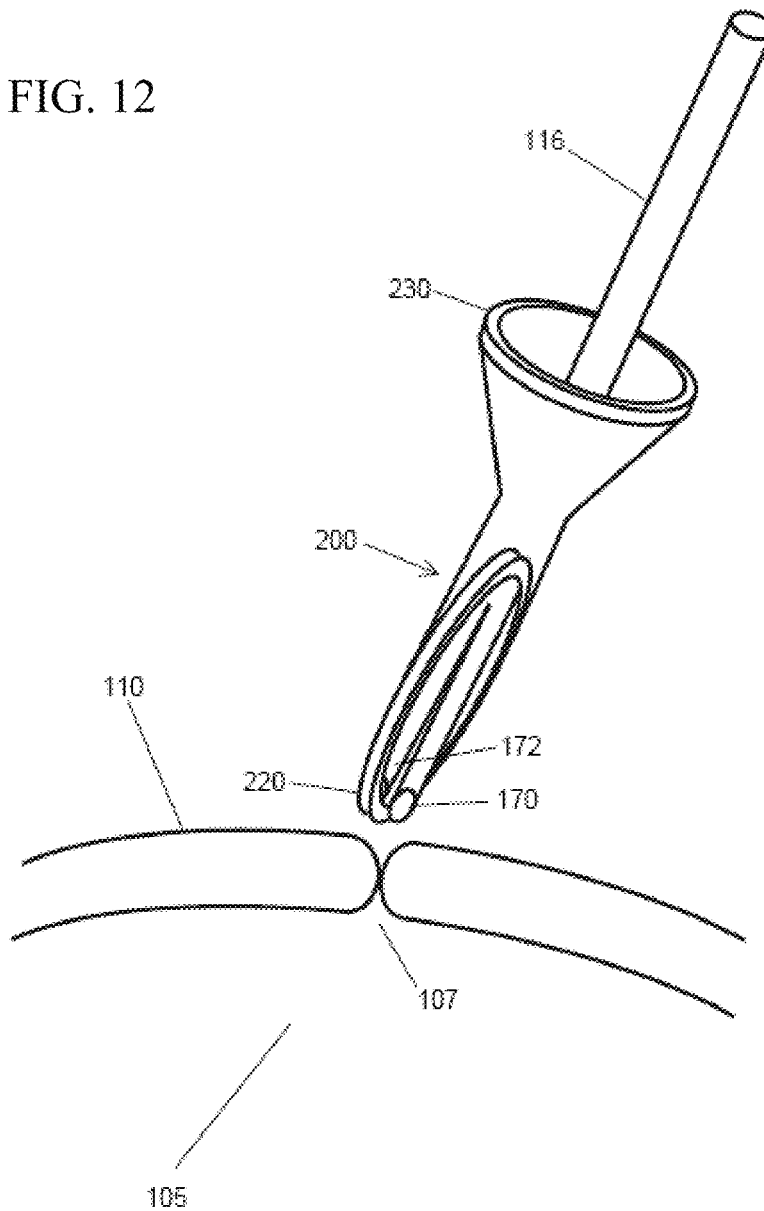


FIG. 13

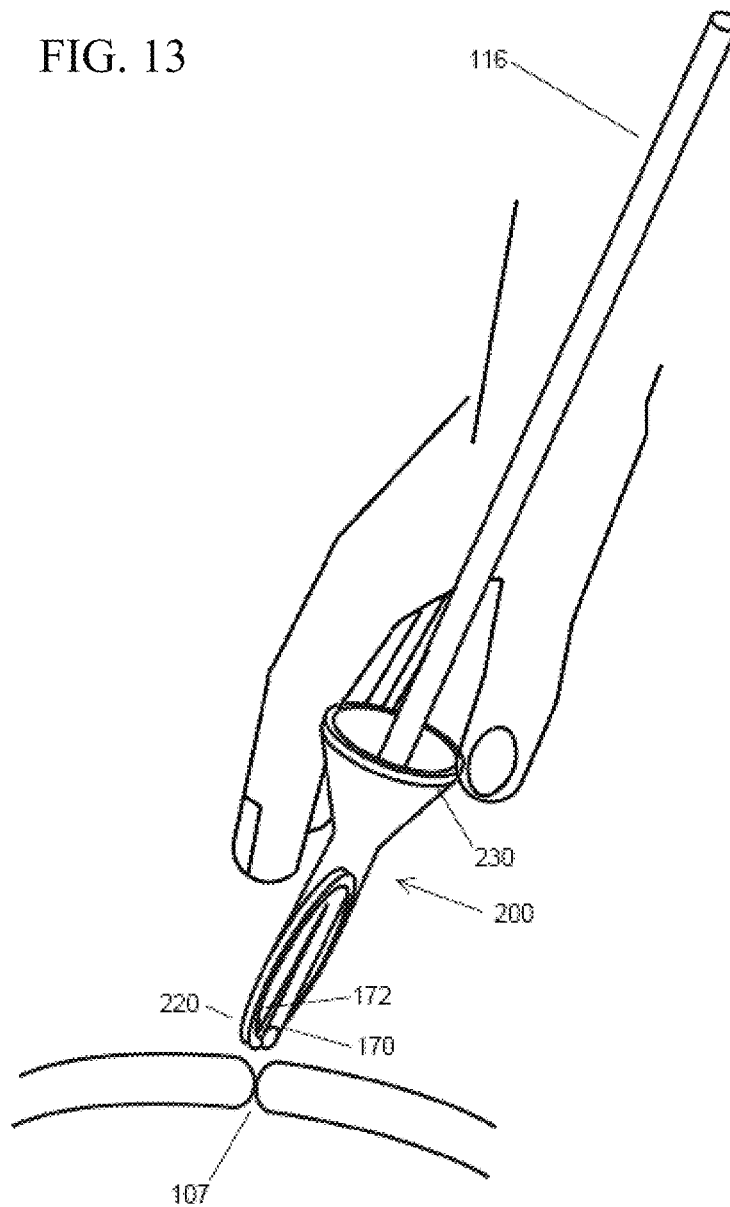
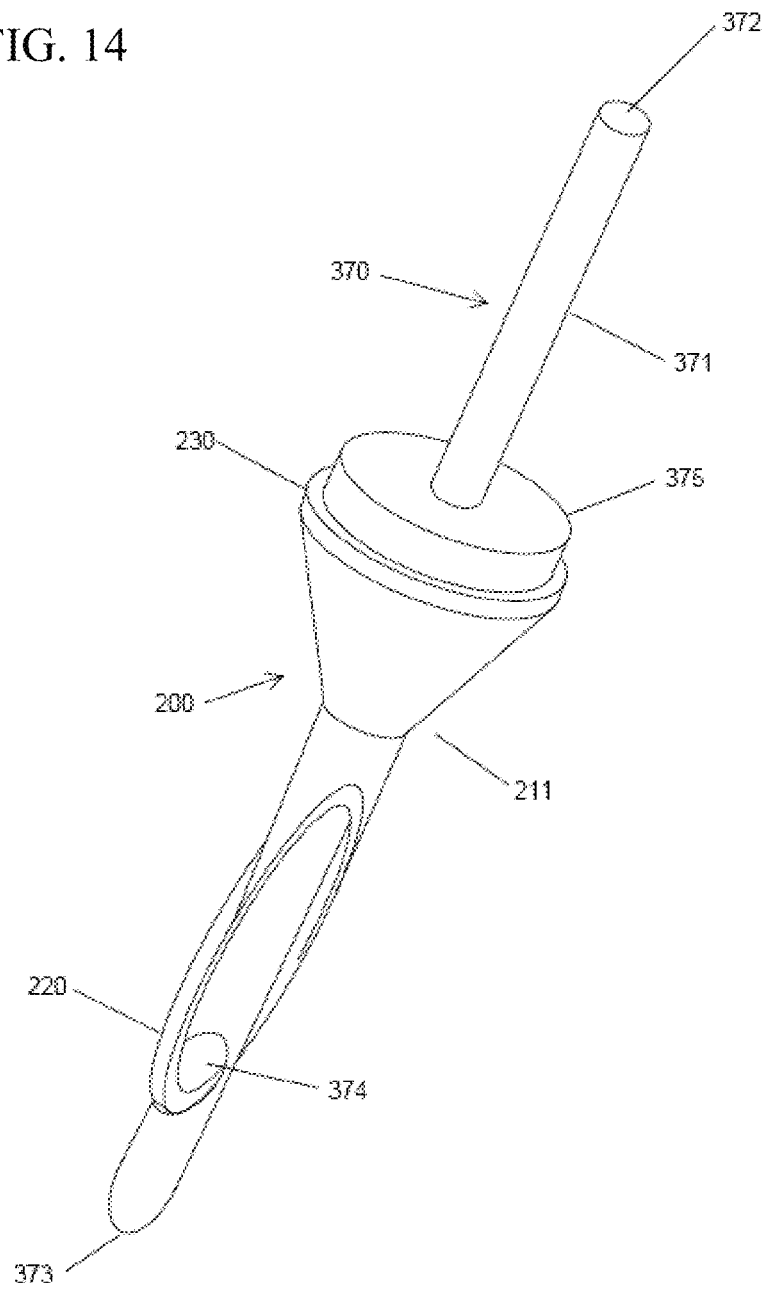


FIG. 14



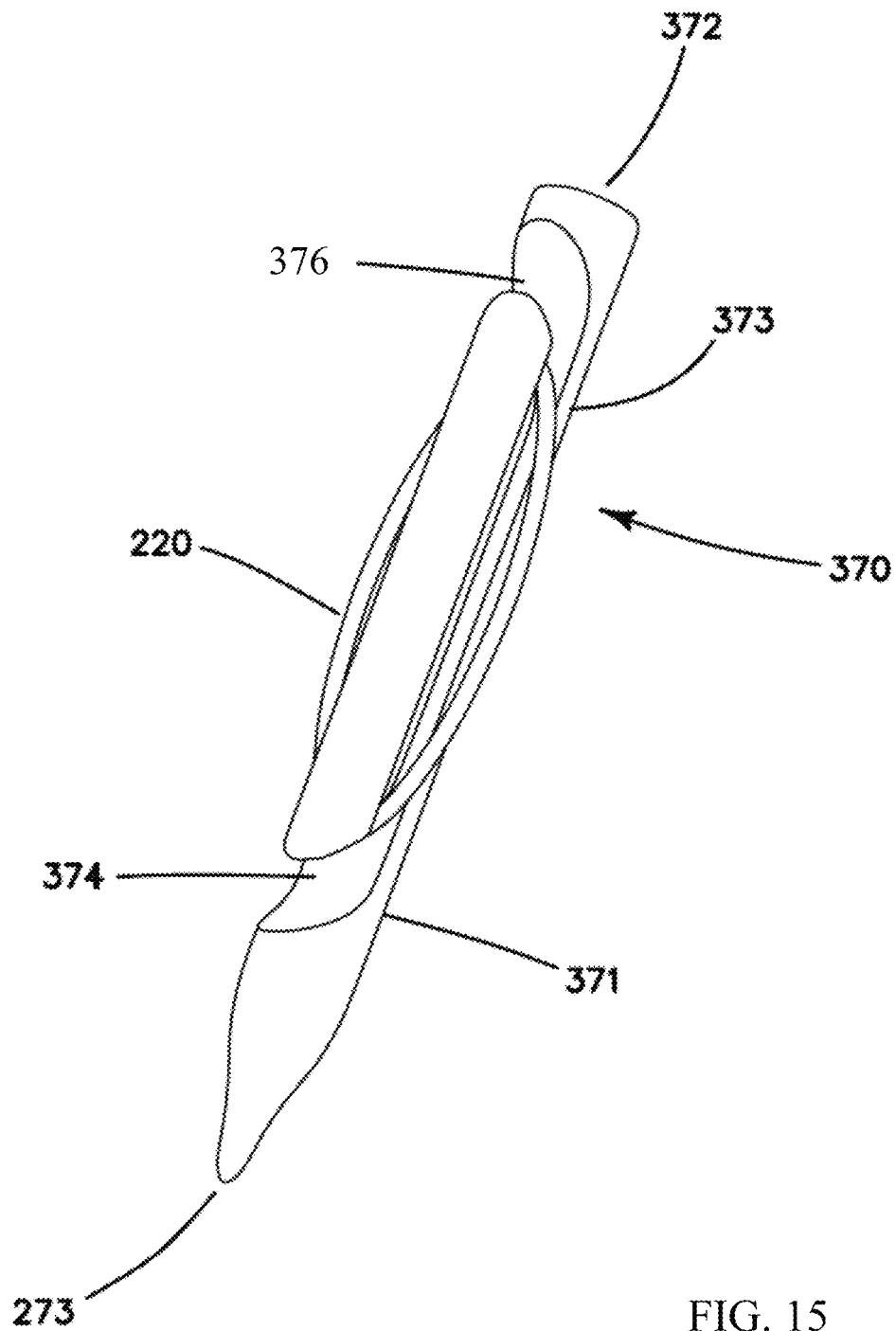


FIG. 15

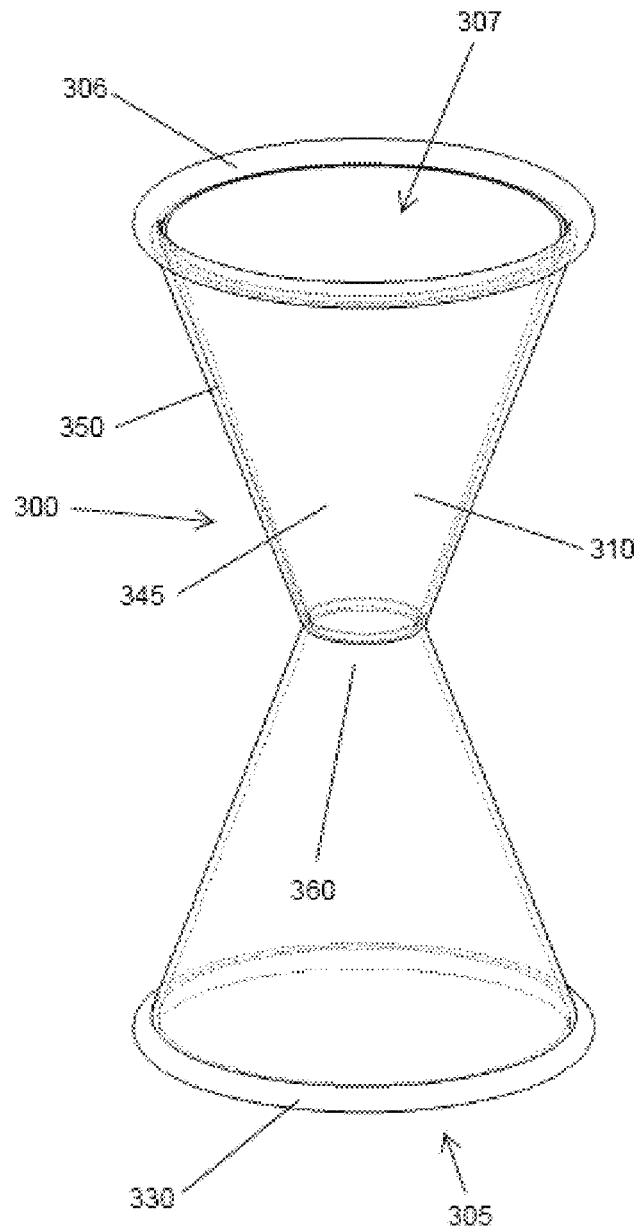


FIG. 16

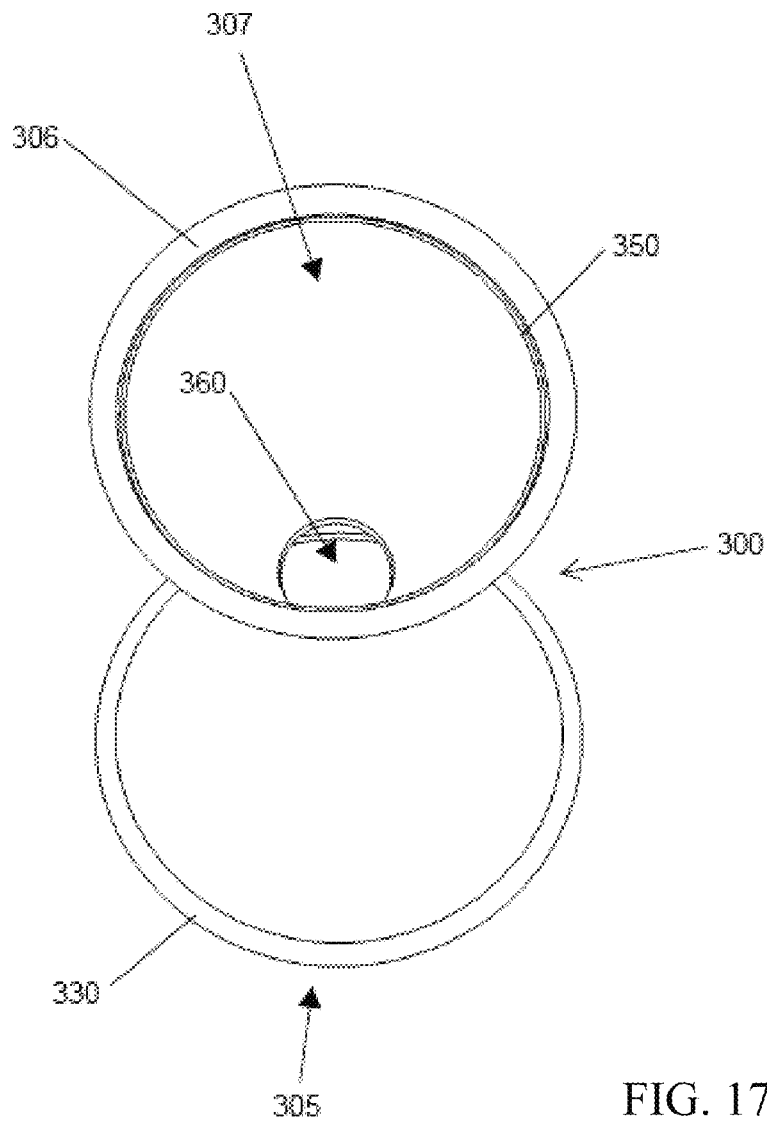
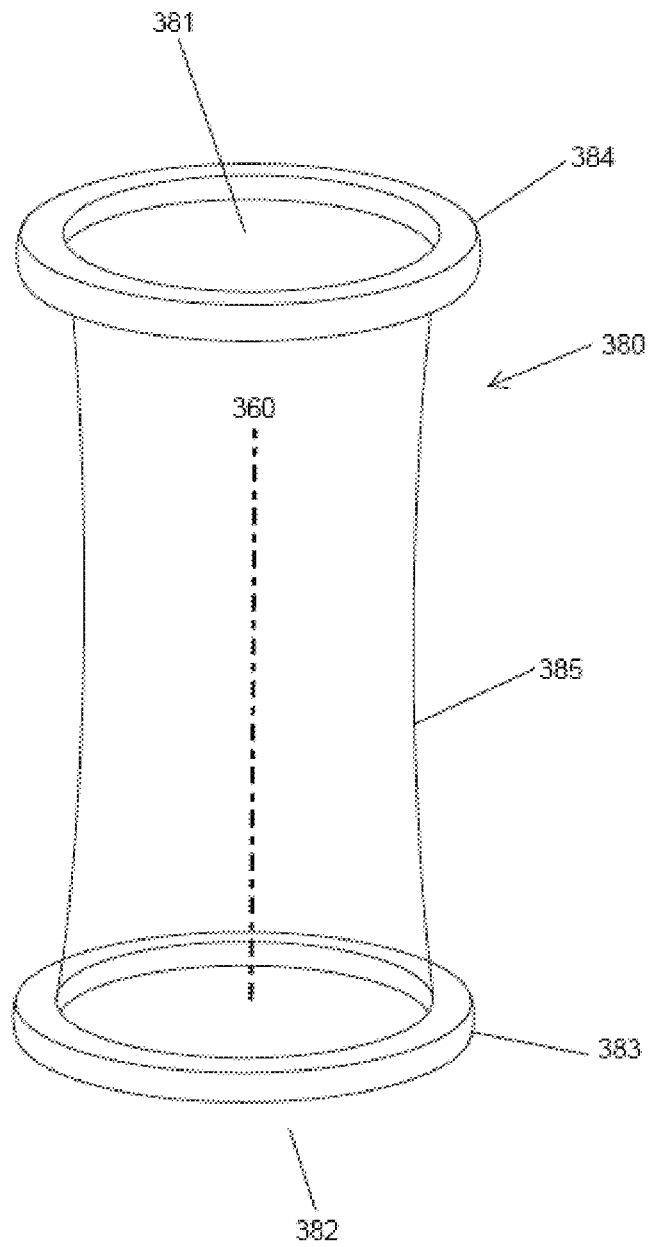
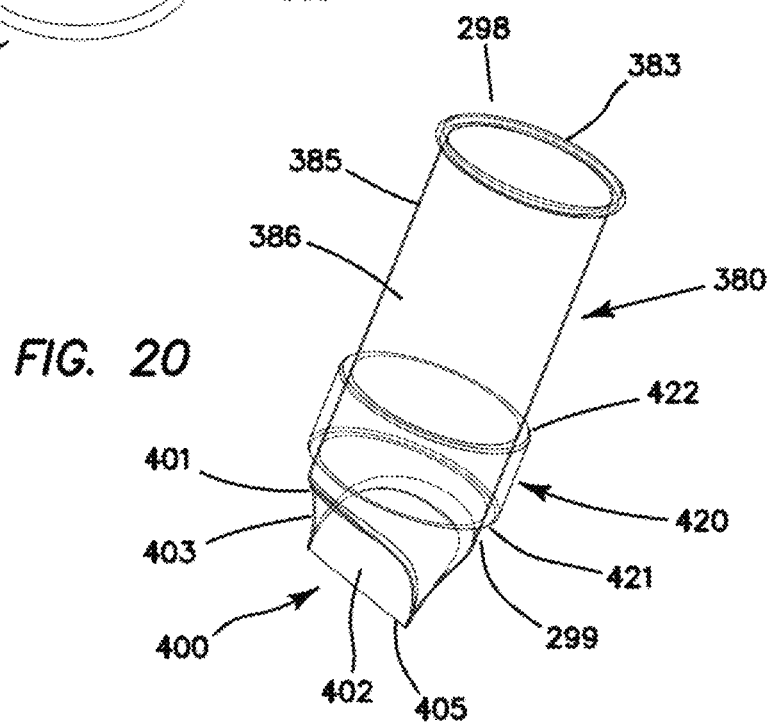
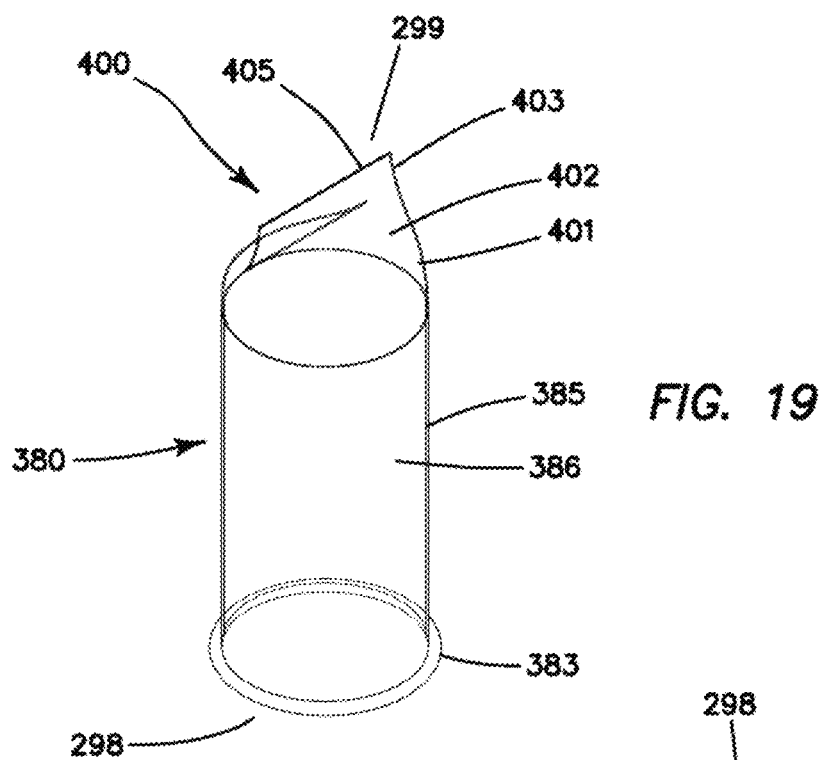
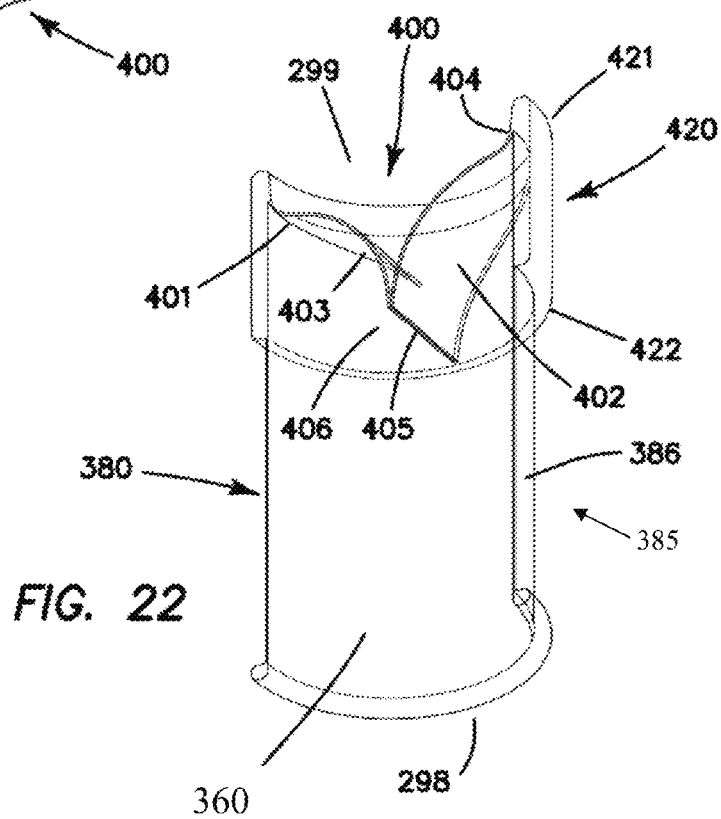
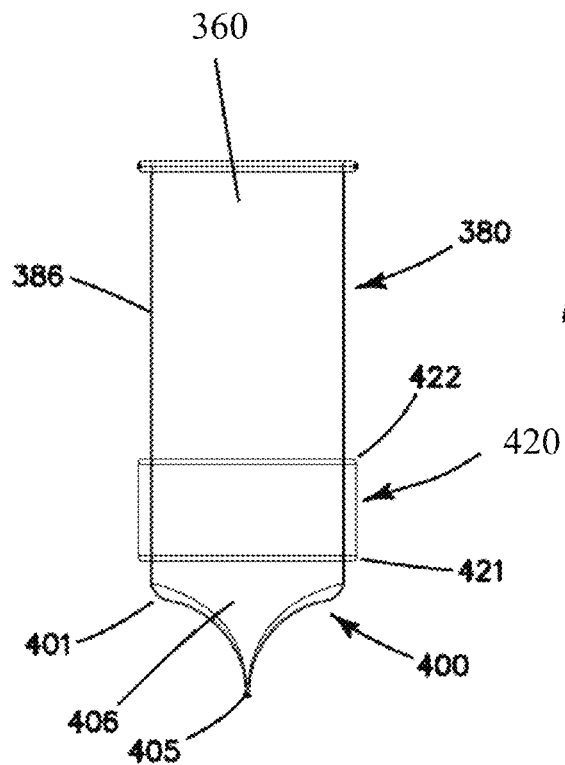


FIG. 17

FIG. 18







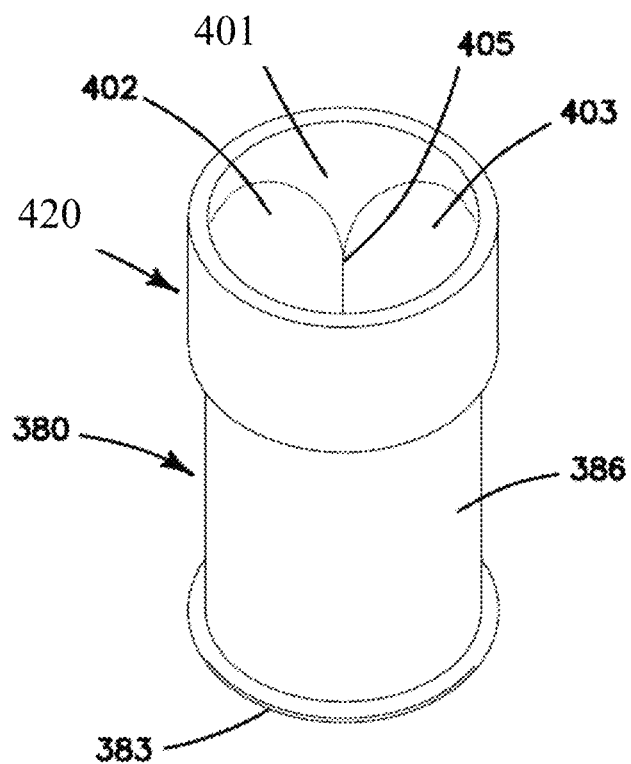
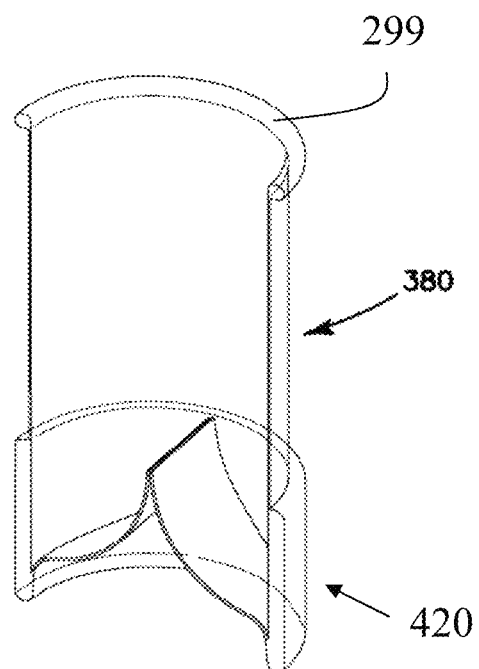


FIG. 23

FIG. 24



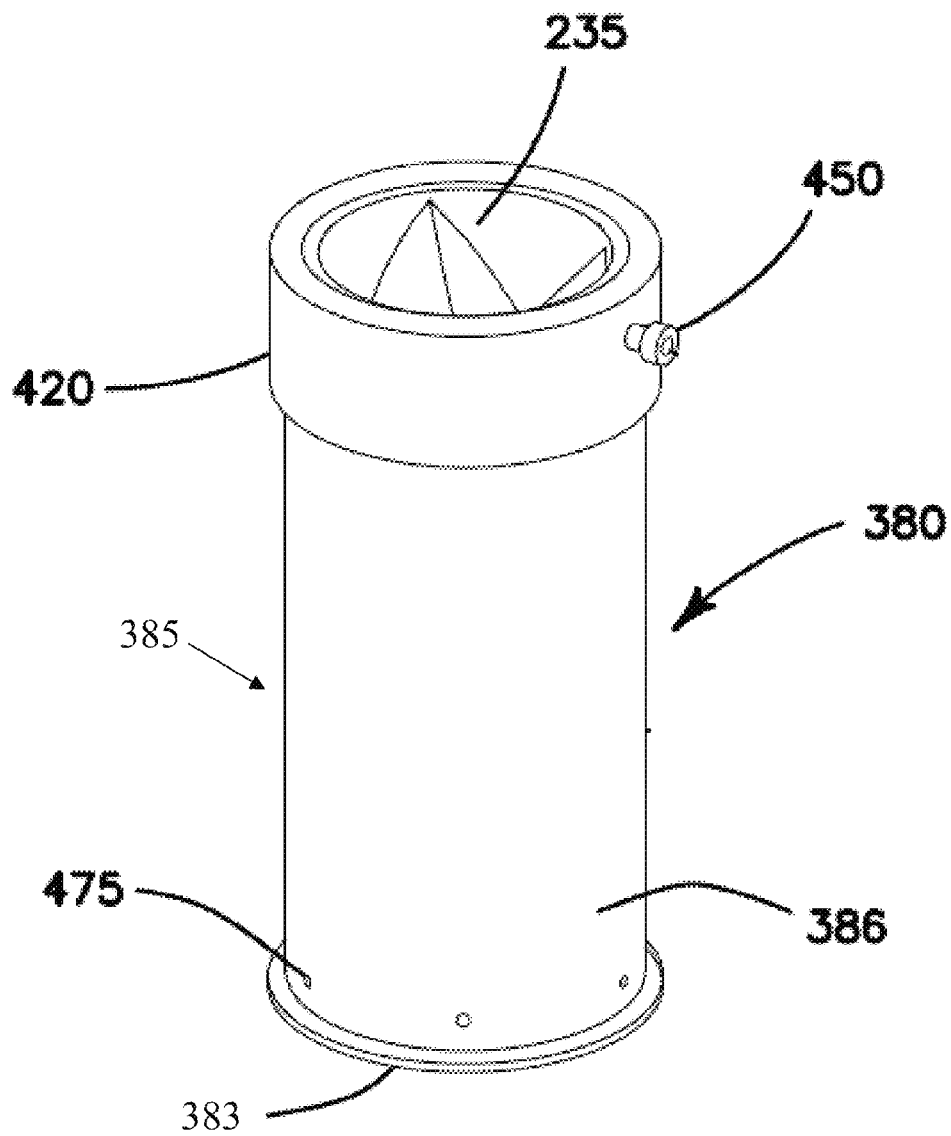


FIG. 25

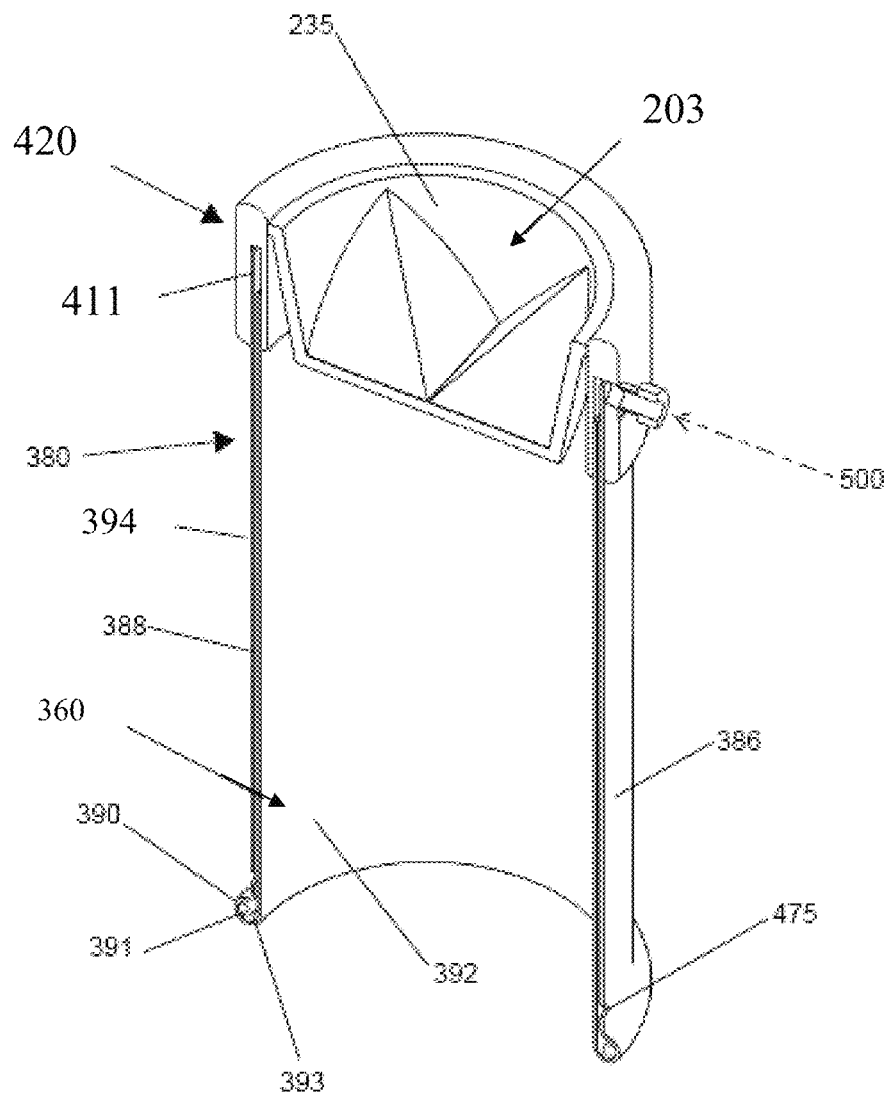
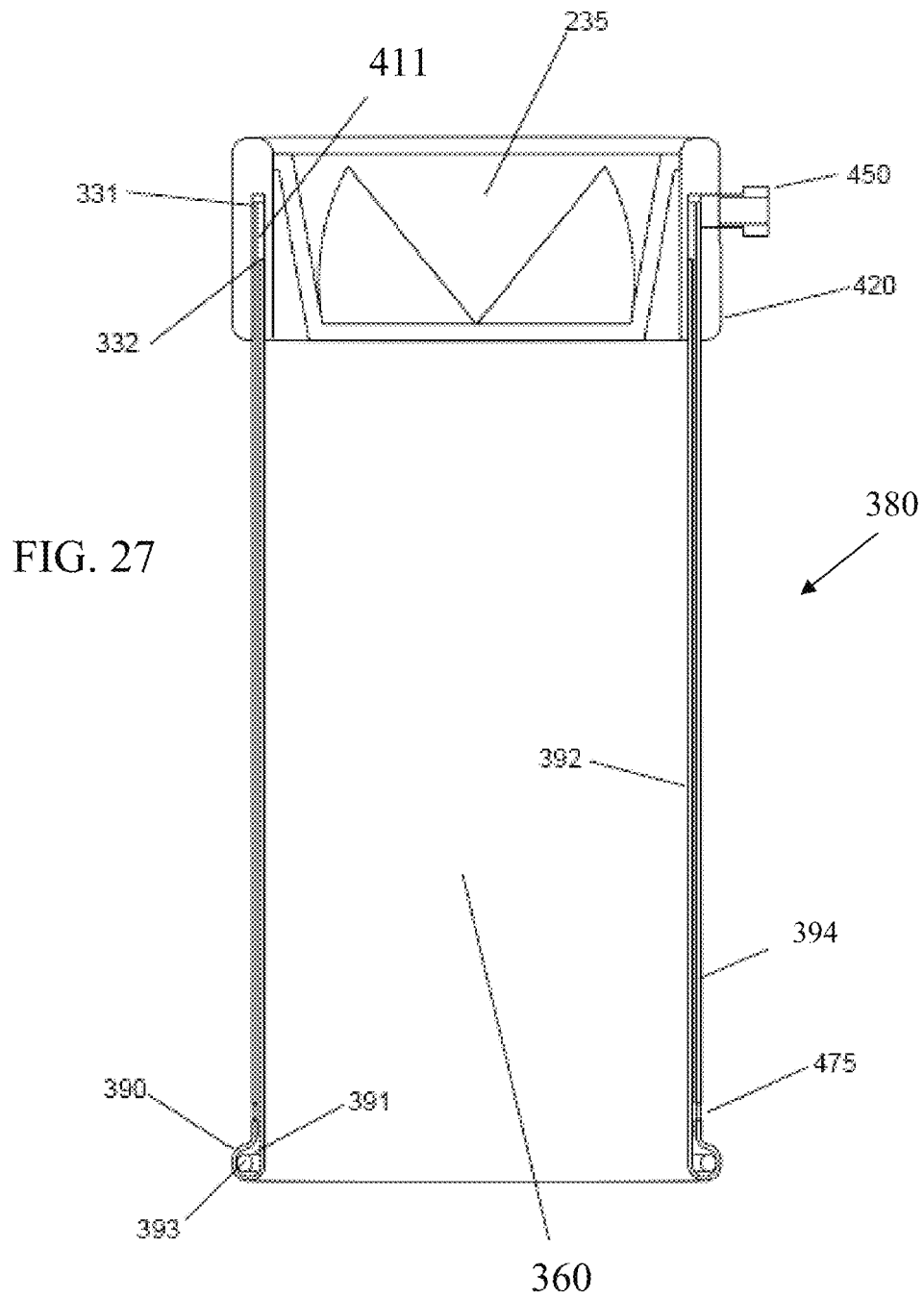


FIG. 26



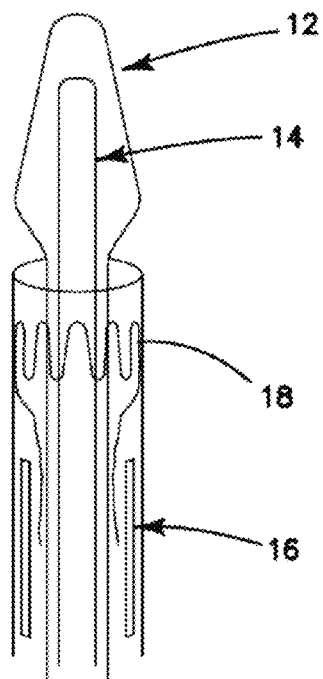


FIG. 28

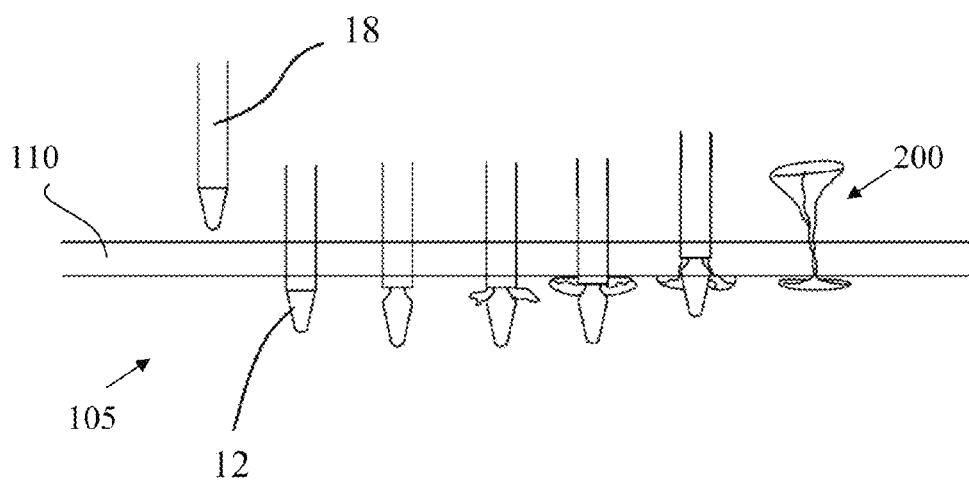


FIG. 29

1

TROCAR SURGICAL SEAL**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application claims the benefit of U.S. Provisional Application No. 61/790,258, filed Mar. 15, 2013, the entire disclosure of which is hereby incorporated by reference as if set forth in full herein.

BACKGROUND

This application relates generally to surgical access systems and more specifically to trocars and other such surgical access devices and specifically to laparoscopic surgical access devices for use in minimally invasive surgical procedures and laparoscopic procedures that result in crowded surgical operating fields.

Surgical access devices are commonly used to facilitate the introduction of surgical instruments through body conduits and into body cavities. A trocar is such a surgical access device and is used in laparoscopic procedures to provide access through the abdominal wall and into the abdominal cavity. In laparoscopic surgeries, the abdominal cavity is commonly inflated or insufflated in order to increase the volume of the working environment. Under these circumstances, one or more valves or seals are provided in a seal housing of the trocar to inhibit the escape of the insufflation gas. The valves form an instrument seal in the presence of an instrument, and a zero seal in the absence of an instrument.

Trocar systems have been of particular advantage in facilitating minimally invasive surgery across a body wall and within a body cavity. This is particularly true in abdominal surgery where trocars provide working channels across the abdominal wall to facilitate the use of instruments within the abdominal cavity. Trocar systems may include a cannula, which provides the working channel, and an obturator that is used to place the cannula across a body wall, such as the abdominal wall. The obturator is inserted into the working channel of the cannula and pushed through the body wall with a penetration force of sufficient magnitude to result in penetration of the body wall. Once the cannula has traversed the body wall, the obturator can be removed.

With the cannula in place in the body wall, various instruments, only one at a time, may be inserted through the cannula into the body cavity. One or more cannulas may be used during a procedure. During the procedure, the surgeon manipulates the instruments in different cannulas, sometimes using more than one instrument at a time. Additionally, during laparoscopic procedures, a trocar can be inserted through a body wall and into body cavity through a small opening, incision or puncture. It has been found that the cannula or tube of the trocar must be larger than the instrument to be used within it. It is the goal of laparoscopic surgeons to keep the incision as small as possible. However, the outer diameter of the cannula can largely drives the size of the incision. Efforts are thus made to reduce the wall thickness, the outer diameter, or both of trocar cannulas and thereby reduce the need for large incisions.

Laparoscopic surgery is also well accepted and has evolved to where surgeons are performing complex procedures through fewer and fewer access ports or devices. In some cases complex procedures may be performed through only one access device. It has become evident that a typical access device such as a trocar may not always be the most efficient tool in a crowded laparoscopic surgical environment. For example, trocars may conflict with one another and compete

2

for space in the operative field. In addition, the bulk of a trocar may not be acceptable as it sometimes restricts movement of surgical instruments and shortens the operative length of the instrument by the height of the trocar seal housing. There is also the restriction associated with the tubular construction of the cannula associated with the trocar. These issues can be of additional concern when a surgeon seeks to perform a procedure from a single site where instrument length and mobility can be critical.

SUMMARY

In accordance with various embodiments, a surgical access device providing instrument access into a patient's body is provided. The access device comprises a first support to be positioned externally to a patient's body, a second support to be positioned within a patient's body and a film passageway having a first end connected to the first support and a second end connected to the second support. The film passageway has a non-adjustable length and is disposed through an opening in a patient's body and in direct contact with the opening in the patient's body. The film passageway has a zero or near zero inner diameter due to compressive forces applied by the patient's body in direct contact with the film passageway in absence of an instrument inserted through the film passageway and provides an instrument seal with an instrument inserted through and in direct contact with the film passageway.

In accordance with various embodiments, a surgical access device providing instrument access through an access platform is provided. The surgical access device comprises a first support, a second support and a film passageway. The first support is positioned externally to an access platform in which the access platform comprises a sealing cap removably coupled to a retractor. The second support is removably insertable through an opening in the sealing cap and is positioned under the sealing cap. The film passageway has a first end connected to the first support and a second end connected to the second support and portions of the film passageway are disposed within the opening in the sealing cap and in direct contact with the opening in the sealing cap. The film passageway has a non-adjustable length and provides a zero seal due to compressive forces applied by the sealing cap in direct contact with the film passageway and in absence of an instrument inserted through the first support and the film passageway. In accordance with various embodiments, the film passageway provides an instrument seal against an outer surface of an inserted instrument and an inner surface of the film passageway with the instrument inserted through the first support and the film passageway.

Many of the attendant features of the present invention will be more readily appreciated as the same becomes better understood by reference to the foregoing and following description and considered in connection with the accompanying drawings in which like reference symbols designate like parts throughout.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side section view of surgical access devices or trocars used in an exemplary laparoscopic procedure.

FIG. 2 is a top view of surgical access devices or trocars used in an exemplary laparoscopic procedure.

FIG. 3 is a side section view of surgical access devices used in a single-site laparoscopic surgical procedure.

FIG. 4 is a top view of surgical access devices used in a single-site laparoscopic surgical procedure.

3

FIG. 5 is an oblique view of a trocar surgical seal or surgical access device and an access platform in accordance with various embodiments.

FIG. 6 is a perspective view of a trocar surgical seal and an access platform in accordance with various embodiments.

FIG. 7 is an oblique view of a trocar surgical seal in accordance with various embodiments.

FIG. 8 is side section view of a trocar surgical seal in accordance with various embodiments.

FIG. 9 is an oblique view of a trocar surgical seal in accordance with various embodiments.

FIG. 10 is an exploded view of a trocar surgical seal in accordance with various embodiments.

FIG. 11 shows a grasper and a trocar surgical seal in accordance with various embodiments.

FIG. 12 shows a trocar surgical seal in accordance with various embodiments being placed.

FIG. 13 illustrates a placement of a trocar surgical seal in accordance with various embodiments.

FIG. 14 is a perspective view of a placement or insertion tool and a trocar surgical seal in accordance with various embodiments.

FIG. 15 is a perspective view of a portion of a placement or insertion tool for use with a trocar surgical seal in accordance with various embodiments.

FIG. 16 is a side oblique view of a trocar surgical seal or surgical access device in accordance with various embodiments.

FIG. 17 is a top oblique view of a trocar surgical seal in accordance with various embodiments.

FIG. 18 is a side view of a trocar surgical seal or surgical access device in accordance with various embodiments.

FIG. 19 is a perspective view of a trocar surgical seal or surgical access device with a formed end in accordance with various embodiments.

FIG. 20 is a perspective view of a trocar surgical seal or surgical access device with a bolster in accordance with various embodiments.

FIG. 21 is a side section view of a trocar surgical seal or surgical access device with a bolster in accordance with various embodiments.

FIG. 22 is a section view of a trocar surgical seal or surgical access device with a bolster and an invaginated portion in accordance with various embodiments.

FIG. 23 is a perspective view of trocar surgical seal with a bolster in accordance with various embodiments.

FIG. 24 is a section view of a trocar surgical seal with a bolster in accordance with various embodiments.

FIG. 25 is a perspective view of a trocar surgical seal or surgical access device having a fluid port in accordance with various embodiments.

FIG. 26 is a perspective section view of a trocar surgical seal having a fluid port in accordance with various embodiments.

FIG. 27 is a side section view of a trocar surgical seal having a fluid port in accordance with various embodiments.

FIGS. 28-29 illustrate an insertion device and a trocar surgical seal or surgical access device in accordance with various embodiments.

DETAILED DESCRIPTION

In accordance with various embodiments, a trocar surgical seal or surgical access device is provided that comprises an elongate body or film passageway to be placed through a patient's body or an access platform to thereby provide a working channel for surgical instruments to be inserted into

4

the patient's body for a minimally invasive surgical procedure. In accordance with various embodiments, the film passageway is generally tubular and in various embodiments does not maintain a particular shape. The trocar surgical seal or surgical access device is non-adjustable and/or is collapsible under pressure or radial or circumferential compressive forces exerted by the body wall, surrounding tissue or the material of the access platform. The trocar surgical seal in any configuration or position does not provide resistance or counteract the forces exerted by the body wall, surrounding tissue or the access platform. The trocar surgical seal provides a gas-tight instrument seal against an outer surface of an instrument inserted there through. In various embodiments, the trocar surgical seal also provide a gas-tight zero seal preventing any gas flow out of the patient in the absence of an instrument inserted there through.

The film passageway in various embodiments is between an inner support and an outer support. The inner support secures the film passageway within the patient's body and the outer support is disposed externally and secures the film passageway to the patient's body. The trocar surgical seal is cannula-less, without a seal housing (housing-less) or both and thus among other things eases manufacturing, assembly, packing, storage and operation of the device. The lack of cannula also reduces potential tissue trauma and the incision or opening size required or used. The lack of seal housing also reduces overall surgical space occupied by the device and reduces port crowding.

Referring now to FIGS. 1 and 2, a laparoscopic arrangement is shown where a plurality of access devices or trocars 113, 114, 115 is placed through a body wall 110 and into a body cavity 105 at strategic locations. For most procedures the trocars are placed strategically to provide optimum visualization, access to target areas and maximize the cosmetic result. Laparoscopic instrumentation 116, 120 and 121 are also shown and are not large bore instruments. Many instruments that once required a shaft diameter of 10 mm to 12 mm are provided with a shaft diameter of 5 mm or less. Optical and digital cameras and systems 120 are also provided such as in a 5 mm format.

Referring to FIGS. 3 and 4, a laparoscopic procedure such as a single-site laparoscopic surgery is shown where trocars 113, 114 and 115 are arranged very close together. It can be seen that rigid trocars having a rigid cannula and a large seal-housing may present concerns where they are used close to each other. In addition, the length of the instruments 116, 120 and 121 may be challenging when using specific length trocars due to for example that the target area 106 may be oblique to the single-site entry 150.

With reference to FIGS. 5 and 6 a surgical access system in accordance with various embodiments of the present invention is provided. In various embodiments, an access platform 152 is shown having a sealing cap that includes a support ring 155 surrounding a penetrable self-sealing seal 160. In various embodiments, the support ring 155 is disposed within the body wall or externally and in various embodiments a tension-able and elongate tube or membrane is affixed or removably coupled to the support ring 155. In various embodiments, an inner support ring 165 is coupled to the tube or membrane 166 and is disposed within the patient. The access platform in one embodiment allows a surgeon to perform a surgical procedure through a single incision or opening. A plurality of trocar surgical seals or surgical access devices 200a, 200b, 200c in accordance with various embodiments of the present invention may be placed through the penetrable seal 160 and thereby provide access into the body cavity 105. The small diameter and very low profile of the access ports or devices

5

200a, **200b**, **200c** allow inserted instruments to be manipulated freely. Also, the low profile and lack of a seal-housing and cannula, bulky, rigid or otherwise, allow the instruments to be inserted further into the body cavity and into hard-to-reach areas.

In accordance with various embodiments, the penetrable seal **160** comprises a gel material, low durometer elastomer, foam, or various combinations thereof and in one embodiment trocar surgical seals may be inserted there through. In one embodiment, the penetrable seal or the gel material includes a triblock or diblock copolymer and in one embodiment also includes oil. In one embodiment, the gel material is coupled to or molded onto the support ring. In one embodiment, the sealing cap is removably coupled to a protector or retractor and in various embodiments the support ring includes a cavity, connector, lever, or any combination thereof, to removably attach the sealing cap to an outer portion or a ring of the retractor. In one embodiment, the retractor is adjustable and configured to roll a sheath around the outer ring that is releasably attachable to the support ring. In one embodiment, the penetrable seal or gel material includes one or more instrument seals, zero seals, or combinations thereof and in one embodiment the surgical access devices may be inserted there through.

Referring now to FIGS. **7-10**, a trocar surgical seal or surgical access device **200**, e.g., trocar surgical seals **200a**, **200b** and **200c**, in accordance with various embodiments of the present invention is shown comprising a generally "hour-glass" shaped elongate body or film passageway **211** having an open proximal end **203**, an open distal end **202** and a narrowed waist **225**. The body **211** appears as a double-ended funnel **210**, **240** having the narrow ends connected. The proximal **203** and distal **202** ends of the body **211** in one embodiment are supplied with enlarged, flexible support rings or first and second supports **220**, **230** that may be elongated as required. The proximal funnel portion **240** in one embodiment may also include or be fitted with a rigid or semi-rigid matching funnel liner or shield **250**. Additionally, in accordance with various embodiments, the proximal end **203**, the distal end **202** or both may include or be fitted with a zero seal **235** to prevent retro-flow of insufflation gas or fluids. In one embodiment, the zero seal **235** is a double-duckbilled elastomeric seal sized and configured to prevent gas from leaking or escaping, e.g., from flowing from the distal end **202** and out the proximal end **203**.

The hour-glass shaped body **211** in one embodiment is constructed from an elastomeric material such as silicone, polyurethane or various rubbers. The narrow waist portion **225** is sized and configured to seal around a range of laparoscopic instruments inserted through the access device. The elastomeric material or material of the film passageway is configured to provide a seal with minimal surface contact with the inserted instrument within the working channel **360** of the trocar surgical seal **200**. The tissue or material surrounding the hour-glass seal body **211** exerts a compressive influence **256**, **257** upon the seal body **211** to assist in perfecting the instrument seal within the working channel **360**. The compressive influence **256**, **257** may provide a zero seal and thus no zero seal **235** may be required to prevent gas flow when there is no instrument within the working channel **360** of the access device **200**. In accordance with various embodiments, the body or film passageway is used without the rigid or semi-rigid shield **250** or the zero seal **235**. Therefore, in accordance with various embodiments, the assembly of an elongate body **211**, a rigid or semi-rigid shield **250** and a zero seal **235** can be separable for use in any combination. Additionally, in one embodiment, the zero seal can be removed for

6

specific or operational uses such as removal of tissue or specimens from within a body cavity. In accordance with various embodiments, the film passageway **211** is made of a material different from the zero seal **235** and the shield **250** and/or, in one embodiment, the shield is made of a material that is different from the film passageway **211** and the zero seal **235**.

The rigid or semi-rigid shield **250** in accordance with various embodiments may be constructed of specifically selected material. For instance, polyethylene, polypropylene or nylon may be selected for use when friction upon an inserted instrument is to be reduced or minimized. The distal opening **252** in accordance with various embodiments may be sized and configured to minimize instrument contact with the elongate body or film passageway material and minimize frictional drag upon an instrument within the working channel **360**. The distal opening **252** is sized and configured to reduce potential instances where a sharp or pointed instrument could puncture or tear the elongate body **211**. The sized distal opening **252** also serves to move the elongate body's orifice or waist portion along with the movement of the inserted instrument so that the orifice is not elongated when an instrument is moved drastically off-axis or obliquely within the working channel **360**. In accordance with various embodiments, if the surgeon requires an instrument to be inserted or placed in an extremely oblique position within the working channel **360**, the zero seal **235** and the shield **250** may be removed from within the elongate body **211** along the shaft of the inserted instrument and then subsequently replaced if desired after movement of the instrument is completed.

FIGS. **11-14** in accordance with various embodiments of the present invention illustrate a method for placing the trocar surgical seal or surgical access device **200**, **300**, **380** through a body wall **110** and into a body cavity **105** or through an access platform **152**. A laparoscopic grasper **116** may be inserted through the proximal end **203** of the trocar surgical seal **200** and advanced to a point where the jaws **170**, **172** of the grasper **116** may clamp upon the distal support ring **220** of the access device. Tension may be placed between the distal support ring **220** and the proximal support ring **230** thereby elongating the distal support ring **220**. The elongated support ring is subsequently inserted through an incision or purposeful defect/opening **107**.

In accordance with various embodiments, an insertion method is illustrated in FIG. **14** and may comprise an obturator or obturator insertion device **370** having a proximal end **372**, a distal end **373** and an elongate body **371**. The proximal end **372** comprises a handle (not shown) sized and configured to allow a surgeon to provide a pushing force to the obturator **370**. The elongate body **371** transfers the pushing force to the distal end **373** of the obturator **370**. The distal end **373** of the obturator **370** in accordance with various embodiments may have a tip **273**, be pointed or configured to provide penetration through tissue or platform material. In one embodiment, the distal end **373** of the obturator **370** may have, at least, one, first holder **374** that engages the distal ring **220** of the access device **200**. The obturator **370** in accordance with various embodiments has a second or proximal holder **375** that is sized and configured to engage the proximal ring **230** of the access device **200** so as to tension the body **211** between the holder **374**, **375** and to reduce the profile of the distal ring **220** for insertion through a body wall or access platform.

Referring to FIG. **15**, the distal portion **373** of an insertion device **370** is shown comprising at least one engaging feature or hook **374** that is sized and configured to retain the distal retention ring **220** or distal end associated with the trocar surgical seal **380** in accordance with various embodiments of the present invention. As illustrated, the distal retention ring

7

220 may be stretched to a low insertion profile by tensioning the ring 220 against the hook or distal retainer 374. After insertion, the tension may be relaxed and the distal ring 220 released from the distal retainer 374. In accordance with various embodiments, a second, proximal retainer 376 is included on the insertion device 370. The distal retention ring 220 of the access device 380 may be tensioned between the distal retainer 374 and the proximal retainer 376 for insertion of the access device through a body wall. The insertion device in one embodiment comprises a handle and elongate shaft 371 along with a point or tip 273 to facilitate insertion of the insertion device through the body wall with no or minimal tissue trauma. In one embodiment, the tip 273 is configured to separate tissue and in various embodiments is bladeless or lacks sharp or cutting edges or surfaces. In various embodiments, the tip is transparent or configured to provide only visual access there through by, for example, a laparoscope and in various embodiments, the tip is transparent or configured to provide visual access therethrough along with insufflation or evacuation access. In various embodiments, the tip or portions of the shaft includes a vent, aperture or configured to provide only insufflation or evacuation access. The transparent, bladeless and/or insufflation tip assists in accordance with various embodiments in which the trocar surgical seal is inserted into a body cavity that is not insufflated or under pneumoperitoneum pressure. In one embodiment, the distal retainer 374, the proximal retainer 376 or both can be disengaged or slid open to release the distal support 220 after insertion through the body wall or access platform.

With reference to FIGS. 16 and 17, a trocar surgical seal 300 is provided in accordance with various embodiments of the present invention. The trocar surgical seal or access device comprises an hour-glass shape constructed from a tubular woven or braided sleeve 310. The woven or braided sleeve may be thermally set to provide the hour-glass shape. A flexible distal support ring 330 may be associated with a distal end 305 of the woven or braided sleeve and a rigid or flexible proximal support ring 306 may be associated with the opposite proximal end 307 of the woven or braided sleeve. The woven or braided hour-glass sleeve in one embodiment may be coated or impregnated with an elastomeric material to form a substantially gas-tight access device. In one embodiment, a rigid or semi-rigid conical shield 350 may be placed within the proximal hour-glass portion 345 of the woven or braided sleeve to provide protection from pointed or sharp inserted instruments within the working channel 360 of the access device 300. If required for complete closure when no instrument is within the working channel 360, a zero seal may be associated with the proximal open end 307, the distal end 305 or both ends of the braided or woven access device 300.

With reference to FIG. 18, a trocar surgical seal 380 is provided in accordance with various embodiments of the present invention. The trocar surgical seal or access device 380 includes an elongate tube or film passageway 385 with a proximal end 381 and a distal end 382. The distal end 382 in one embodiment may include a flexible support ring 383 that may be deformed to allow positioning through a body wall or an access platform. The proximal end 381 of the tube 385 in one embodiment may be fitted with a rigid or flexible support ring 384 and in accordance with various embodiments will remain outside a body wall or seal platform. The tube 385 extends between the rings 383 and 384 and may be compressed by the tissue or access platform material through which the tube extends. In one embodiment, a rigid or semi-rigid conical shield may be placed within the film passageway 385 to provide protection from pointed or sharp inserted instruments within the working channel 360 of the access

8

device 300. If required for complete closure when no instrument is within the working channel 360, a zero seal may be associated with the proximal end 381, the distal end 382 or both ends of the film passageway.

In accordance with various embodiments, the trocar surgical seal includes a braid, fabric or woven sleeve 310 or a portion thereof integrated into a film passageway 211, 385, both of which are configured to extend through the body wall or access platform. The braid provides a low-friction, expandable lead-in. The braid serves to prevent direct contact between the body wall and the inserted instrument which can occur in the absence of the film when the tissue extrudes through interstitial spaces of the braid. By preventing direct contact between the body wall or tissue and an inserted instrument, the frictional forces associated with advancement and withdrawals of an instrument are reduced. In accordance with various embodiments, the film passageway prevents direct contact between the body wall and the braid serves to maintain the integrity or protection of the opening in the body wall during insertion, advancement, and withdrawal of a surgical instrument.

In one embodiment, as a surgical instrument is inserted into the trocar surgical seal or access device, the braid expands to the size, e.g., the width or diameter, of the inserted instrument and directs the instrument through the trocar surgical seal. The film passageway 211, 385 can be formed from relatively distensible or relatively non-distensible film materials including polyolefin, polyurethane, polyethylene, polypropylene, nylon, and polyester. As an instrument is inserted into the braid, the braid expands while the body wall or surrounding body tissue resists expansion. As such, the body wall or surrounding body tissue forces or applies a compressive radial or circumferential load or force against the surgical seal to sealingly engage the outside diameter of an inserted instrument while eliminating direct frictional contact between the inserted instrument and the tissue.

In accordance with various embodiments, the film passageway 211, 385 can be formed of a thin material with a thickness that is in the range of 0.0005" to 0.002". The braid in accordance with various embodiments is expandable and can accommodate a large range of instrumentation sizes which can range from 3.5 mm to 16 mm in diameter. The braid and the film passageway of the surgical seal 200, 300, 380 eliminate or reduce the potential for an instrument to tear or catch the trocar surgical seal if the instrument is inserted off-center or off-axis with respect to the longitudinal axis of the surgical access device or the body opening.

In one embodiment, bifurcated instruments can damage the trocar surgical seals especially if they are inserted or removed off-center or off-axis. The braid and film passageway combinations serve to direct the instrument through the aperture of the surgical seal. The braid and the film work to expand the aperture of the trocar surgical seal in response to the insertion of an instrument. This expansion action of the braid and the film passageway enables the diameter of the surgical seal aperture to be minimized. The minimized diameter of the trocar surgical seal's aperture allows the surgical seal to sealingly engage a large range of inserted instruments. With other access devices, it can be challenging to minimize the diameter of an instrument seal's aperture and also avoid puncture in response to the insertion of bifurcated instruments such as clip appliers.

The braid and the film passageway 211, 385 of the trocar surgical seal also serve to reduce the force required to insert and advance an instrument through the surgical seal. The coefficient of kinetic friction (f) for the braid/film verses a metal or polymer instrument shaft is significantly less than

that for an elastomeric seal verses a metal or polymer instrument shaft. The coefficient of kinetic friction values range from 0.15 to 0.5 for polymers such as polyester verses steel, whereas the coefficient of kinetic friction values for elastomers versus steel range from 1.6 to 10. The braid in combination with the film passageway eliminates direct contact between the shaft of an inserted instrument and the tissue and therefore minimizes the frictional forces required to insert and advance an instrument through the trocar surgical seal.

The film passageway **211, 385** in one embodiment is a 0.0005" polyolefin film. In one embodiment, the braid is woven from a 0.001" diameter polyester monofilament is positioned adjacent to or bonded or embedded to the film passageway. The braid in one embodiment is flared at its proximal end, distal end or both to enable ease of insertion and withdrawal of instruments. In one embodiment, a ring, such as a polyethylene ring, is bonded to the distal ends of the braid and/or film passageway to prevent inversion or migration during instrument withdrawal. In accordance with various embodiments, instruments include laparoscopic and endoscopic instruments, probes, scopes, trocars, cannulas and other surgical access devices or instruments.

The braid in accordance with various embodiments is made from natural or synthetic monofilament thread materials. For example, the braid may be made from polyester, Kevlar, carbon fiber, Gore-Tex (expanded PTFE), Nomex, Nylon, fiber glass, cotton, polypropylene, and ceramic. The braid, film passageway or both in accordance with various embodiments are made from a hygroscopic or superabsorbent polymer monofilament material. As such, the braid, film passageway or both can absorb fluids transferred from inserted or withdrawn instruments to prevent fluids from subsequently transferring from the access device to an inserted instrument such as a laparo scope to prevent reduction in visualization through the laparoscope.

The braid in accordance with various embodiments is permanently coated or treated to reduce friction between inserted or withdrawn instruments and the braid. For example, the coating or treatment of the braid include hydrophilic polymer coatings, Teflon (PTFE) coatings, cyanoacrylate coatings, Parylene coatings, plasma surface treatments, and chlorination treatments. The braid and film passageway in accordance with various embodiments are mechanically locked in place by including an additional ring that would trap the proximal ends of the braid and film passageway between the ring.

In accordance with various embodiments of the present invention, the trocar surgical seal or access devices **200, 300, 380** do not have a predefined shape and accommodate an elongate surgical instrument inserted therein. The access device may be generally tubular if held from the proximal or distal end and with gravity acting thereon. The shape of the access device **200, 300, 380** is defined by compressive forces exerted on the access device by for example a body wall. The access device extends from or near the outside of the body cavity and distally towards the inside of the body cavity. The shape of the access device is also defined by instrument inserted into the working channel of the access device. As such, in accordance with various embodiments, unlike other trocars or surgical access devices, the access device **200, 300, 380** is collapsible or does not exert a radial or expansive force against the body wall or opening in the patient. Hence, the access device does not force an opening or attempt to maintain a predefined opening or shape, e.g., a tubular shape of a cannula or retractor. The access device thus minimizes potential tissue trauma and reduces incision or opening size. Also, in accordance with various embodiments of the present invention, the access device **200, 300, 380** has open and unob-

structed proximal and distal ends. As such, a seal housing is not present, used or attachable to the proximal or distal end of the access device thereby minimizing surgical space occupied by the access device and preventing port crowding. Accordingly, in various embodiments, the trocar surgical seal **200, 300, 380** lacks or is without a seal housing, a cannula and/or a retractor and is in direct contact with the body wall or opening in the patient or access platform.

In accordance with various embodiments of the present invention, the trocar surgical seal or access devices **200, 300, 380** having a generally tubular, hour-glass or various other shapes are sized and configured to accommodate an elongate surgical instrument inserted therein. In various embodiments, the body or film passageway **211, 385** of the access devices has at a first open end. In various embodiments, the first open end includes a first support and in various embodiments the first support includes a compliant ring, a proximal or external bolster or collar and a seal sized and configured to prevent flow of gas in one direction. The body of the access devices in accordance with various embodiments includes a compliant ring at a second open end. The body or film passageway **211, 385** of the access device in various embodiments is constructed from a very thin, durable, elastomeric material or a very thin non-elastomeric material that is easily compressed by the tissue of the body wall through which it has been inserted. Elastomeric materials may include silicone, polyurethane, latex, poly-isoprene and the like. Non-elastomeric may include material such as polyolefin, polyester, polyethylene or the like.

In accordance with various embodiments of the present invention, the trocar surgical seal or access devices **200, 300, 380** may be introduced through a body wall and into a body cavity through an incision or opening that is considerably smaller than the incision required by a typical access device or trocar. For instance, a trocar that accommodates 5 mm instruments requires an incision that accommodates a 7 mm cannula or tube. The outer diameter of the cannula or tube is responsible for the larger incision size. The access device **200, 300, 380** for example comprises a body constructed of a film material having a wall thickness of 0.003"-0.005". The nearly negligible wall thickness allows for an incision size that is substantially smaller than that required by traditional trocars. In accordance with various embodiments of the present invention the incision size could be smaller than the designated size of the instrument indicated for use. For example, an incision, through which a 5 mm instrument is to be used, may be reduced to approximately 3 mm. The inserted instrument will temporarily dilate or enlarge the tissue defect and perfect a gas-tight seal between the body wall, film passageway and the instrument. The small incision or opening size is useful as a small incision imposes a compressive, circumferential sealing load upon an inserted instrument; results in less scarring of subject tissue; generally requires no mechanical closure such as stitches or staples; and is less likely to become hernia site than a larger incision.

In accordance with various embodiments, the film passageway **211, 385** is made of material, e.g., polyolefin, and/or has a thickness, e.g., between 0.0005 to 0.002 inches, that is not able to extend in a longitudinal direction or resists extension or forces to stretch the material in a longitudinal direction. In accordance with various embodiments, the film passageway **211, 385** is made of material and/or has a thickness that is not able to extend or resists extension or forces to stretch the material in a horizontal direction or a direction traverse to the longitudinal direction except as it is urged to unfold under the influence of an inserted instrument within the film passageway.

11

In accordance with various embodiments of the present invention, the body or film passageway of the access device **200**, **300**, **380** may be constructed by welding thin sheet-film into a tube or may be blow molded or otherwise formed into a generally tubular shape. In one embodiment, an irradiated ultra-thin-walled, cross-linked polyolefin tube that may be post-formed into a desired shape or condition by the application of heat to all, or a portion of the tubular member is used. This manufacturing process may also facilitate attachment of the tubular structure to proximal and distal supports or rings without the use of adhesives. In various embodiments, the film **211**, **385** includes various slip agents such as waxes, soaps, diatomaceous earth, silicone oils, and fluoropolymers to reduce the drag force on inserted instruments.

With reference to FIGS. **19-24** in accordance with various embodiments of the present invention a trocar surgical seal or access device **380** is provided. The access device **380** has a distal end **298**, a proximal end **299** and an elongate body or film passageway **385** extending between the distal end **298** and proximal end **299**. The film passageway **385** comprises an elongate mid section **386**. A distal end of the elongate mid section **386** in one embodiment supports or includes a “ring-shaped” retainer or support **383**. In accordance with various embodiments, the material from which the elongate mid section **386** extends and curves along a peripheral portion **401** into tapers, folds or curved surfaces **402**, **403** meeting at a slit **405** and thereby forming a zero seal **400**.

In various embodiments, the proximal end of the elongate mid section **386** supports or includes a bolster or ring **420**. In accordance with various embodiments, the material of the elongate mid section **386** extends through the bolster **420** in a proximal direction and subsequently extends distally to a peripheral portion **401** into curved surfaces **402**, **403** and meeting at slit **405** to form the zero seal **400**. The bolster **420** stabilizes the seal and the mid section relative to each other and the patient's body or access platform. The bolster **420** in one embodiment has a proximal portion **421** and a distal portion **422** in which the height or distance between the portions is about a third of the height of the mid section to assist in stabilizing the seal relative to mid section, the patient's body, the access platform or instruments inserted therein. The bolster **420** also in one embodiment provides a stable structure to form or attach the seal or to maintain the zero seal under insufflation pressure. As such, in one embodiment, the area or cavity **406** adjacent to the seal **400** and the working channel **360** remains sealed in the absence of an inserted instrument.

In accordance with various embodiments, the material of the elongate mid section **386** extends through the bolster **420** proximally and is subsequently invaginated distally to form a self-closing or zero seal **400** in the presence of pressure gradients within the cavity **406** and lumen or working channel **360** of the access device between the distal end of the elongate mid section **386** and the proximal end of the elongate mid section **386** or along an inner surface or portion of the seal. The self-closing seal **400** comprises inverted, invaginated portions **402**, **403** that are formed by returning the proximally extending mid section portion to within the lumen **360** of the elongate mid section **386**. The invaginated portion is configured to exhibit a substantially planar cross-section resembling a “duck-billed” seal. In one embodiment, pneumoperitoneum pressure further maintains or assists in the maintenance of the film portions **402**, **403** in a sealed condition in the absence of an inserted instrument. In accordance with various embodiments, the seal **400** is similarly formed in addition to or only at the distal end **298**. In accordance with various embodiments, the bolster **420** is thicker, wider, and

12

higher and/or is made of a material that is more rigid, thicker or both than the first support, the second support, the film passageway or any combination thereof. In various embodiments, the bolster is made of a material that is different from the first support, the second support, the film passageway or any combination thereof.

Referring now to FIGS. **25-27**, a trocar surgical seal or access device **380** in accordance with various embodiments comprises a film passageway **211**, **385** that comprises a double-walled, concentric structure where a tubular body is inverted upon itself so that a first end **331** of the body adjoins a second end **332** of the body. A ring shaped support **393** in one embodiment may be inserted into the space **391** between the walls **392**, **394** and urged into the formed distal pocket **390** where the film is folded. The two adjoining ends **331**, **332** are subsequently attached to a bolster **420** in accordance with various embodiments.

In various embodiments, near the distal end of the inverted sleeve body, one or more holes or openings **475** may be formed in the outer wall **394**. The one or more holes are smaller in diameter than the working channel **360** or lumen through the film passageway. A fluid connector **450** in one embodiment may be connected to the external bolster **420** that communicates with the distal openings **475** in the outer wall **394** of the access device **380** through a space or channel **388** between the walls **392**, **394** of the inverted sleeve body or an opening or channel **411** between the bolster **420** and the walls **392**, **394**. Gas or fluid may thus be administered or removed through the access device, for example, by connecting a gas supply **500** to the fluid connector **450** of the bolster **420** and allowing gas to flow between the walls **392**, **394** and through the distal openings **475** in the outer wall **394** of the access device **380**. In one embodiment, a gas or fluid passageway is provided to/from the fluid connector **450** directly through the bolster or the film passageway and into the working channel, e.g., between the zero seal and the film passageway. The gas pressure within the trocar surgical seal and between the coaxial walls can provide additional sealing capability to the trocar surgical seal **380** between the penetrated tissue and an inserted instrument within the working channel **360** of the access device **380**. The trocar surgical seal also remains unhoused and in direct contact with the body wall.

In FIGS. **28** and **29**, an insertion device in accordance with various embodiments is shown. The insertion device includes an obturator **12** and in one embodiment includes an optical viewing channel **14** to ensure proper placement of the trocar surgical seal within a patient's body or access platform. The support or distal portion of the access device is shown disposed near the distal end of the insertion tube **18** with a movable deployment slide **16** to eject the trocar surgical seal out of the tube and into the patient. FIG. **29** further illustrates exemplary steps or stages of an insertion of the trocar surgical seal in accordance with various embodiments of the present invention starting with the trocar surgical seal outside the patient's body and within an insertion or deployment device and ending with the trocar surgical seal deployed and disposed through the patient's body.

In accordance with various embodiments described throughout, the trocar surgical seal **200**, **300**, **380** is capable of accommodating irregularly shaped instruments or objects and in various embodiments is a nearly friction-free, self-sealing, utilizing a small incision or opening and having a low-profile but allowing the use of full-sized laparoscopic instruments. In accordance with various embodiments, a trocar surgical seal **200**, **300**, **380** is provided and in various embodiments has a body or film passageway with an open and unobstructed lumen there through and unobstructed and open

13

ends. The film passageway **211, 385** in various embodiments is radially collapsible or compressible under radial or circumferential force exerted by a body wall or surrounding body tissue and thus does not maintain a particular shape, e.g., tubular. In one embodiment, the film passageway **211, 385** can be flattened or compressible or collapsible longitudinally and/or radially to assist in packing or storing of the access device. A first support and a second support are provided on each respective ends of the film passageway in accordance with various embodiments. In accordance with various embodiments, movement of the first or second supports or the film passageway relative to each other provides insufficient force to enlarge the inner diameter of the film passageway or to retract the opening in the patient's body or the access platform. Retraction of the body wall prevents an instrument or zero seal from forming or causes the seal to leak.

The second support is to be disposed internally relative to the patient's body and may be constructed of a flexible material so that the support may be deformed for insertion through a body wall or an access platform. The second support may be shaped or compressed by a tensioning or insertion device to provide a low profile insertion shape. The second support in various embodiments is circular and has structural stability to maintain a circular shape in use. In various embodiments, the second support is connected to a second, open end of the film passageway. In one embodiment, the first and second supports have the same inner and/or outer diameters and/or are made of the same material.

The film passageway **211, 385** in various embodiments is a formed as a tube that is constructed of a durable but flexible material having a thin wall thickness. In various embodiments, the film passageway **211, 385** is made of polyethylene, polyester, polyurethane, nylon or the like. The film passageway **211, 385** in various embodiments may be constructed of or may include a thin film or a woven fabric. The film passageway **211, 385** in various embodiments is connected at the opposite, first, open end to a first support that is to be disposed externally relative to the patient's body. In various embodiments, the first support **220, 330, 384** is generally circular in shape and in various embodiments may be constructed of a more rigid material than that of the second support, the film passageway or both. As such, in one embodiment, the first support **220, 330, 384** is made of a material that is different from the film passageway, the second support or both. In accordance with various embodiments, the first support **220, 330, 384** is shaped or dimensioned to prevent rotation of the first support or twisting of the film passageway. In one embodiment, the first support **220, 330, 384** is shaped to not permit rolling or rotational movement about itself. In accordance with various embodiments, the first support **230, 330, 384**, the second support **220, 330, 383**, the film passageway **211, 385** or any combination thereof are not inflatable or include an inflatable or fillable bladder. As such, the profile of the trocar surgical seal can remain low and proximate to the body wall and thereby reduce or prevent port crowding or clashing and increase the ability to move or angle an instrument off axis. Additionally, the trocar surgical seal can resist or prevent retraction or retracting of the body wall or the access platform that may cause leak paths or weaken the intended instrument seal.

In accordance with various embodiments, the film passageway **211, 385** is made of material, e.g., polyolefin, or has a thickness, e.g., between 0.0005 to 0.002 inches, that prevents winding of the film passageway around the first support and prevents the film passageway from retracting the opening in the patient's body. In one embodiment, the film passageway **211, 385** has different shapes in an unconstrained condition.

14

In one embodiment, the film passageway **211, 385** is made of a material that is puncture resistant and/or low friction. The width of the working or access channel **360** or the inner diameter of the film passageway **211, 385** in one embodiment are dimensioned to minimize the drag or friction forces associated with insertion, movement, and withdrawal of instruments.

In various embodiments, a valve may be inserted or connected to the first support **230, 330, 384** and comprises a pressure-driven seal that closes upon itself when a pressure differential exists. In various embodiments, the access device **200, 300, 380** may include a zero seal, such as a duck-bill or double duck-bill seal, to prevent back-flow of gas or fluids. In accordance with various embodiments, a zero seal is connected to the first support **230, 330, 384** or the film passageway **211, 385**. In accordance with various embodiments, a zero seal is connected to the second support **220, 330, 383**. The zero seal in various embodiments comprises an elastomeric material for example at least one polymer resin, rubber, synthetic rubber, polyisoprene, silicone, as well as blends, mixtures, copolymers or composites thereof. In one embodiment, the zero seal is made of a material that is different from the material of the shield, the film passageway, the first support, the second support or any combination thereof.

In accordance with various embodiments, an outer surface area of the film passageway **211, 385** in contact with the patient's body or an access platform is greater than an inner surface area of the film passageway in contact with an inserted instrument. In accordance with various embodiments, the film passageway is constructed to exhibit a predefined shape, such as an hour-glass shape as viewed from the side. The throat or narrowest point along the film passageway's path is sized and configured to represent the instrument-size range for the access device itself. For instance, a throat size of 5.5 mm will accommodate 5 mm instruments. This dedicated profile and throat size can obviate the need for a primary instrument seal because the constrictive pressure on the film passageway from the tissue or wall through which it is inserted compresses the film passageway's material upon the outer surface of the inserted instrument shaft.

In accordance with various embodiments, the film passageway **211, 385** has a length with a range of sizes of 1.5"-4.5". In one embodiment, the film passageway **211, 385** has a length that accommodates different thicknesses of a patient's abdominal wall and in one embodiment a variety of sizes are provided, e.g., small (1.5"-2.5"); medium (2.5"-3.5"); and large (3.5"-4.5"). In one embodiment, the film passageway **211, 385** has a maximum inner diameter of 17 mm, an outer diameter greater than 17 mm or both. In one embodiment, the film passageway **211, 385** has an inner diameter of about 5-7 mm, an outer diameter greater than 7 mm, and/or first and/or second supports having diameters of about 10-12 mm to support 7 mm or smaller instruments. In one embodiment, the film passageway **211, 385** has an inner diameter of about 5-13 mm, an outer diameter greater than about 13 mm, and/or first and/or second supports having inner diameters of about 15-17 mm to support 13 mm or smaller instruments. In one embodiment, the film passageway **211, 385** has an inner diameter of about 5-17 mm, an outer diameter greater than about 17 mm, and/or first and/or second supports having inner diameters of about 20-24 mm to support 17 mm or smaller instruments. In one embodiment, the film passageway **211, 385** is impregnated or otherwise incorporated with antibacterial or antimicrobial agents, coating, particles, laminations or other compositions such as iodine, antibiotics, silver, triclosan, biocides or combinations thereof.

15

In accordance with various embodiments, the first, external support **230, 306, 384** may comprise a molded elastomeric double duck-billed valve having an integral support or ring associated with the open or proximal end. The double-duck-billed valve provides protection from a sharp or pointed instrument. If the sharp or pointed tip is inadvertently directed toward the side wall of the access device, the tip will be deflected by the valve away from the wall and towards the center or throat portion of the film passageway.

The double-duck-billed valve in various embodiments has a substantially conical overall shape as it is viewed from the side. As viewed from the open, proximal end, the circular shape of the proximal end is resolved into two crossing flat sealing portions. When there is more pressure on the external surface of the valve than on the internal surface, the valve is urged to close. When an instrument is inserted into the valve, the valve does not resist the instrument or present inordinate friction upon the motion of the instrument. In various embodiments, the double-duck-billed valve may include one or more guard members that conform to the internal shape of the valve. This embodiment provides additional protection for the sheath during insertion of sharp or pointed instruments.

In accordance with various embodiments, a dilator may be associated with the open, proximal end of the trocar surgical seal **200, 300, 380** that assists in the opening of the narrow portion of the sheath or film passageway. In various embodiments, one or more dilators or portions thereof are urged forward by the off-axis insertion of an approaching instrument tip to provide a clear and corrected path for the incoming instrument. The one or more dilators or portions thereof subsequently retract when the instrument is in place. A compressive force upon the one or more dilators or portions thereof while within the channel, e.g., an hour-glass shaped channel, of the film passageway urges the one or more dilators or portions thereof proximally and out of the channel.

In accordance with various embodiments, the film passageway **211, 385** is collapsed prior to insertion into the patient's body and remains collapsed in an operational state when no instrument is within the film passageway. In accordance with various embodiments, an insertion or placement device is provided having a handle to be held by a surgeon, an elongate shaft and a distal portion sized and configured to engage the first, inner support of the trocar surgical seal and provide or restrain the support with a shape and profile for insertion through a body wall and into a body cavity. In various embodiments, the insertion device may include one or more retainers, e.g., two distal opposing retainers that engage the first support **230, 306, 384** and stretch the support into an oval or elongate shape. The retainers in various embodiments may include opposing hooks and in various embodiments one or more of the hooks may be alternately moved toward each other or apart from each other.

In accordance with various embodiments, an opening of the access platform in contact with the film passageway **211, 385** exerts a radial or circumferential compressive force that is greater than a drag force of an instrument inserted through the film passageway. In accordance with various embodiments, the access platform has an outer diameter at least two times larger than a maximum inner diameter of the film passageway with an instrument inserted therethrough. In accordance with various embodiments, the opening in the access platform is preformed or made upon insertion of the second support being inserted through the access platform and in accordance with various embodiments the access platform comprises a gel material coupled to a cap or support ring. In

16

accordance with various embodiments, the trocar surgical seal **200, 300, 380** lacks a seal housing, a cannula or retractor.

As shown in various embodiments, a trocar surgical seal **200, 300, 380** is provided for use in a surgical procedure and in particular a minimally invasive procedure. The trocar surgical seal seals a working channel provided by the surgical access device thereby preventing the escape or facilitating the supply of insufflation gases prior to or during a surgical procedure. The trocar surgical seal can seal the working channel with an instrument disposed through the seal and in accordance with various embodiments in the absence of such an instrument. The working channel provides a path or access into a patient's body cavity. The trocar surgical seal in accordance with various embodiments includes multiple layers or components having different characteristics to facilitate or enhance the sealing characteristics of the seal to seal the working channel of the surgical access device.

The trocar surgical seal **200, 300, 380** sealingly engages surgical instruments of various diameters to prevent loss of pneumoperitoneum or to prevent loss of carbon dioxide or other surgical gas during use of such instruments in a laparoscopic procedure. The trocar surgical seal also facilitates the insertion and manipulation of laparoscopic instruments by directing away from the body wall and the body or wall of the surgical seal and by minimizing the friction produced between the surgical seal and the inserted instruments. The trocar surgical seal provides a positive seal with respect to instruments inserted through the trocar surgical seal to prevent loss of pneumoperitoneum during laparoscopic surgical procedures. In various embodiments, in the absence of an inserted instrument, the insufflated abdominal pressure or peritoneal pressure, which typically ranges from 6.5 mm Hg to 17 mm Hg, forces or assists in forcing the film passageway together to sealingly close the instrument channel to prevent loss or leakage of pneumoperitoneum. Pneumoperitoneum pressure in accordance with various embodiments also further forces or assists in forcing the film passageway to form around the shaft of an inserted instrument to prevent excessive loss of carbon dioxide or other insufflation gas. In accordance with various embodiments, the access device **200, 300, 380** can be inserted into a body cavity that is not insufflated or under pneumoperitoneum pressure. In some embodiments, a patient's bone structures, such as the ribs or other such bodily structures, provide radial or circumferential compressive forces that collapse the film passageway of the trocar surgical seal **200, 300, 380**.

In accordance with various embodiments, the use of a trocar surgical seal or surgical access device **200, 300, 380** can dramatically reduce the number of components used to achieve instrument access and pneumo-sealing. Often trocars and trocar seals are complicated, have large profiles both in diameter and height off the patient, and are of a fixed rigid diameter. In various embodiments, the trocar surgical seal also conforms to the tissue and is thereby less traumatic. The low profile of the trocar surgical seal or access device also reduces "port crowding". An obturator or introducer in various embodiments eases placement of the access device. The obturator or introducer in various embodiments may be loaded with multiple access devices, staged up behind each other, collapsed longitudinally and/or radially, axially down the shaft of the introducer and deployed one-by-one for multiple access sites. In various embodiments, the access device **200, 300, 380** may also accommodate various instrument sizes as opposed to fixed-size or rigid cannulas. In accordance with various embodiments, the trocar surgical seal **200, 300, 380** is a replacement for typical trocars including seal hous-

17

ings, cannulas and other surgical access devices or platforms or facilitates the use or operation of other surgical access devices or access platforms.

Although this application discloses certain embodiments and examples, it will be understood by those skilled in the art that the present inventions extend beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Further, the various features of these inventions can be used alone, or in combination with other features of these inventions other than as expressly described above. As such, it should be appreciated that although specific combinations of embodiments and features or aspects of various embodiments may not be explicitly described such combinations however are contemplated and within the scope of the present inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims.

The invention claimed is:

1. A surgical access system providing instrument access through and into a patient's body, the system comprising:

a) an access platform comprising:

a retractor including:

a proximal ring configured to be positioned outside the patient's body,

a distal ring configured to be positioned inside the patient's body, and

a flexible tube connecting the outer ring to the inner ring, the flexible tube arranged to enlarge an opening in the patient's body; and

a sealing cap removably connected to the outer ring of the retractor, the sealing cap comprising a penetrable self-sealing seal; and

b) a trocar surgical seal comprising:

a bolster positioned externally to the self-sealing seal of the sealing cap,

a ring being removably insertable through an opening in the self-sealing seal of the sealing cap and positioned under the self-sealing seal of the sealing cap, and a thin compressible tubular film defining a passageway therethrough, the film having:

a proximal end connected to the bolster and having inverted invaginated portions formed by returning proximally portions of the film within the passageway of the film, and

a distal end connected to the ring of the trocar surgical seal,

the tubular film being disposed within the opening in the self-sealing seal of the sealing cap and in direct contact with the opening in the self-sealing seal of the sealing cap,

the film being compressed and defining a zero seal due to compressive forces applied by the self-sealing seal of the sealing cap in direct contact with the tubular film and pressure applied by insufflation gas within the patient's body; and

wherein the tubular film is collapsible and the passageway defined therethrough has a zero inner diameter due to the compressive forces applied by the self-sealing seal of the sealing cap in direct contact with the tubular film.

2. The surgical access system of claim 1 wherein an inner surface of the film seals against an outer surface of an inserted instrument with the instrument inserted through the bolster and the film and the passageway defined therethrough.

18

3. The surgical access system of claim 1 wherein the self-sealing seal at the opening of the sealing cap in contact with the film exerts a circumferential compressive force that is greater than a drag force of an instrument inserted through the film and the passageway defined therethrough.

4. The surgical access system of claim 1 wherein the sealing cap has an outer diameter at least two times larger than an outer diameter of the bolster.

5. The surgical access system of claim 1 wherein the opening in the sealing cap is made upon insertion of the ring of the trocar surgical seal through the self-sealing seal of the sealing cap.

6. The surgical access system of claim 1 wherein the bolster is movable relative to the film and the film in direct contact with the self-sealing seal remains to have the zero inner diameter due to compressive forces applied by the self-sealing seal of the sealing cap.

7. The surgical access system of claim 1 wherein the film and the passageway defined therethrough is in a collapsed state prior to insertion through the sealing cap and remains in the collapsed state in an operational condition until receiving instruments after insertion of the film through the sealing cap.

8. The surgical access system of claim 1 wherein an outer surface area of the film passageway in contact with the self-sealing seal of the sealing cap is greater than an inner surface area of the film passageway in contact with an inserted instrument.

9. The surgical access system of claim 1 wherein the film comprises an elongate mid-section, and the bolster having a proximal portion and a distal portion in which a distance between the proximal and distal portions is a third of a height of the elongate mid-section of the film.

10. The surgical access system of claim 1 wherein the film is made of a thin material with a thickness having a range of 0.0005 to 0.002 inches.

11. The surgical access system of claim 1 wherein the film is a thin polyolefin film.

12. The surgical access system of claim 1 wherein the film is a 0.005 inch thick polyolefin film.

13. The surgical access system of claim 1 wherein the film includes slip agents to reduce a drag force on inserted instruments.

14. A surgical access system for providing instrument access through and into a patient's body, the system comprising:

a) an access platform comprising:

a retractor including:

a proximal ring configured to be positioned outside the patient's body,

a distal ring configured to be positioned inside the patient's body, and

a flexible tube connecting the outer ring to the inner ring, the flexible tube arranged to enlarge an opening in the patient's body; and

a sealing cap removably connected to the outer ring of the retractor, the sealing cap comprising a penetrable self-sealing seal; and

b) a trocar surgical seal comprising:

a bolster positioned externally to the self-sealing seal of the sealing cap,

a ring being removably insertable through an opening in the self-sealing seal of the sealing cap and positioned under the self-sealing seal of the sealing cap,

a zero seal connected to the bolster, and

a thin compressible tubular film defining a passageway therethrough, the film having:

a proximal end connected to the bolster, and

19

a distal end connected to the ring of the trocar surgical seal,
the film being disposed within the opening in the self-sealing seal of the sealing cap and in direct contact with the opening in the self-sealing seal of the sealing cap,
the film being compressed and defining a zero seal due to compressive forces applied by the self-sealing seal of the sealing cap in direct contact with the tubular film and pressure applied by insufflation gas within the patient's body; and
wherein the tubular film is collapsible and the passageway defined therethrough has a zero inner diameter due to the compressive forces applied by the self-sealing seal of the sealing cap in direct contact with the tubular film.

* * * * *

20